# FT PharmaSuite®



## EQUIPMENT TRACKING PHASES

### RELEASE 11.01.00
### FUNCTIONAL REQUIREMENT SPECIFICATION

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FT PharmaSuite® 11.01.00 - Functional Requirement Specification Equipment Tracking Phases

# Contents

FT PharmaSuite® 11.01.00 - Functional Requirement Specification Equipment Tracking Phases

# 1  Introduction

This document details the requirements of the functions implemented by the phases specific to equipment tracking. The phases are executed in the Production Execution Client of PharmaSuite.

Each requirement is composed of a name (e.g., Preview mode) and a unique identifier (e.g., GID-1234567) and is extended with its business attributes (GxP Relevance, Business Impact) and its compliance attribute (21 CFR Part 11 Relevance).

For requirements with **Framework capability** as identifier, see "Functional Requirement Specification Execution Framework" for their unique identifier, [A1] (GID-2667997)

The revision history lists the changes made to the document with the previous FactoryTalk PharmaSuite release as the comparison baseline. It provides individual tables for "Updated", "Added", and "Deleted" requirements that juxtapose the previous approved version with the new approved version of an item.

**Typographical Conventions**

This documentation uses typographical conventions to enhance the readability of the information it presents. The following kinds of formatting indicate specific information:

| Bold typeface | Designates user interface texts, such as |
|---|---|
| | <ul><li>window and dialog titles</li><li>menu functions</li><li>panel, tab, and button names</li><li>box labels</li><li>object properties and their values (e.g., status).</li></ul> |
| Monospaced typeface | Designates code examples. |

FT PharmaSuite® 11.01.00 - Functional Requirement Specification Equipment Tracking Phases

# 2   Recipe and Workflow Configuration for Equipment Tracking

This section provides an overview of equipment tracking within workflows and process orders.

## 2.1   Phases

The following phases are available for equipment tracking:

- Identify equipment (GID-2667990)
  The **Identify equipment** phase allows to identify an equipment entity or an equipment entity group and to bind the entity to the context in which it is being used (e.g. order, workflow). Additionally, the phase allows to build an equipment entity group. As a prerequisite for binding, the phase performs fit-for-purpose checks. For verification purposes, an already bound equipment entity can be re-scanned within the same unit procedure context.

- Change equipment status (GID-2667991)
  The **Change equipment status** phase allows an operator to set an FSM-related status of a previously identified equipment entity.
  The phase neither supports equipment graphs that are maintained in Data Manager - Equipment nor equipment entity groups.

- Trigger graph transition (GID-2667992)
  The **Trigger graph transition** phase allows an operator to change an equipment graph-related status of a previously identified equipment entity or equipment entity group (parent entity and its child entities) by executing a graph trigger.

- Separate equipment (GID-2667993)
  The **Separate equipment** phase allows an operator to separate an equipment entity group. Either the entire group is separated into single entities or a single entity or a sub-group is separated from a main group.
  Based on the phase configuration, a separated equipment entity can keep its binding status and a separated sub-group can keep its grouping by retaining its relations to its own child entities.

- Unbind equipment (GID-2667994)
  The **Unbind equipment** phase allows an operator to release a previously bound equipment entity or all equipment entities of a group before a unit procedure is finished. Thus, the entity or entity group can be identified within another unit procedure context while the current unit procedure is still running.

- Show equipment list (GID-2667995)
  The **Show equipment list** phase allows to show a list of equipment entities with the current values of a defined set of their specification properties and their runtime data, such as runtime properties and graph-related data.

■ Generate template-based equipment (GID-2667996)
The **Generate template-based equipment** phase allows to generate one or more equipment entities with attributes, properties, and equipment graphs based on a configured template equipment entity.

## 2.2   Binding of Equipment

An equipment entity or equipment entity group can only be used in the context of one unit procedure at any given time. To ensure the exclusive usage, the **Identify equipment** phase does not only identify an equipment entity, but also binds it to the current unit procedure if all relevant checks have passed successfully. As soon as an equipment entity has been identified (i.e. successfully scanned, but not yet bound) or bound, it is no longer available in the context of any other unit procedure.
Equipment entities are either released automatically upon completion of a unit procedure or they can be released explicitly with the **Unbind equipment** phase.

All binding- and release-related activities are tracked in the equipment logbook (if maintained).

## 2.3   Grouping of Equipment

An equipment entity group consists of a parent entity and one or more child entities. Thus, a child entity that has children is the sub-parent to a sub-group, which itself belongs to a main group that has its main parent.
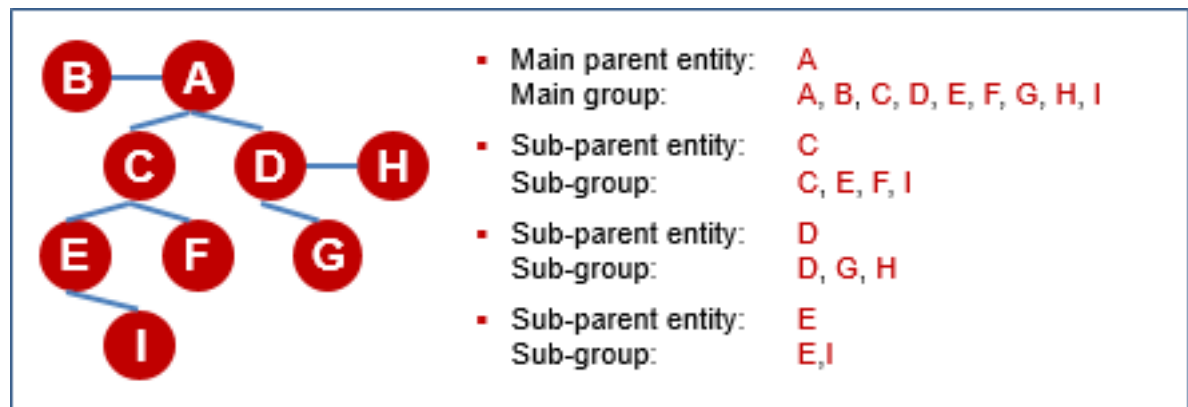


*Figure 1: Structure of an equipment entity group*

Equipment entity groups support different use cases on the shop floor:

■ Setting up a production line or work center.

■ Assembling and disassembling equipment.

■ Grouping equipment entities that only share a loose connection (e.g. equipment entities that are placed on a tray to be sterilized in an autoclave).

In general, the grouping of equipment entities is considered to be runtime data that is primarily executed on the shop floor. All grouping-related actions are tracked within the logbook (if maintained) of the affected equipment entities.

In order to support ad-hoc repair use cases, the assignment between parent and child entities can also be updated by authorized users within Data Manager - Equipment. If the grouping is updated while a parent entity is already bound to a unit procedure, the system automatically records the update as an exception in the context of this unit procedure.

For examples how to configure the related equipment tracking phases in support of different grouping and separation scenarios, see

- create an equipment entity group (GID-2669510),
- identify an equipment entity group for usage (GID-2669511),
- re-identify an already bound equipment entity or entity group (GID-2669512),
- trigger a graph transition on an equipment entity group (GID-2669513), and
- separate an equipment entity group (GID-2669514).

### 2.3.1  Creating an Equipment Entity Group

The **Identify equipment** phase supports two identification scenarios: identify a **parent entity** and identify the **child entities** that are added to the parent entity.

An equipment entity can only belong to one equipment entity group at a given point in time.

For creating of an equipment entity group, the following configuration rules apply to the process parameters of the **Identify equipment** phase:

- Parent entity of group (GID-2426749) must only be defined to identify a child entity to be added.
- Identify in current binding context (GID-2426750) must be set to **Yes** if the new child is already bound to the same unit procedure context, otherwise it must be set to **No**.
- Identification mode (GID-2426751)can be set to **Entity or group** (if both is allowed), **Single entity required** (if only a single entity must be identified), or **Entity group required** (if only an entity group must be identified), but must not be set to **Child entity (already bound)**.
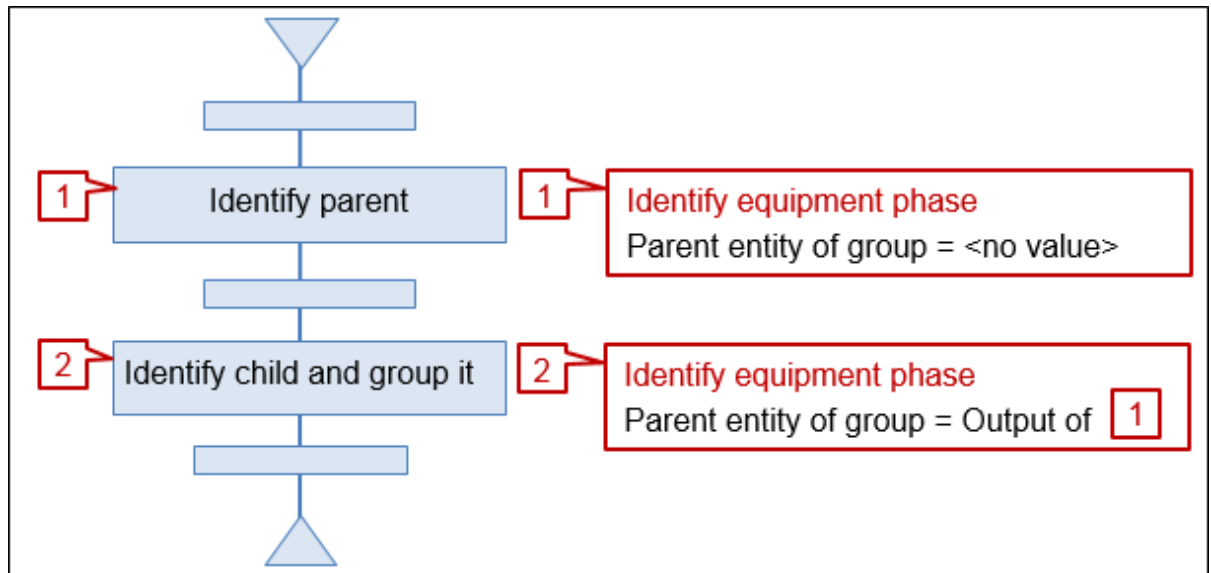
*Figure 2: Example configuration - group two equipment entities*

The subsequent figure shows the assembly of an equipment entity group (Compactor) that finally will contain a sub-group (Crusher).
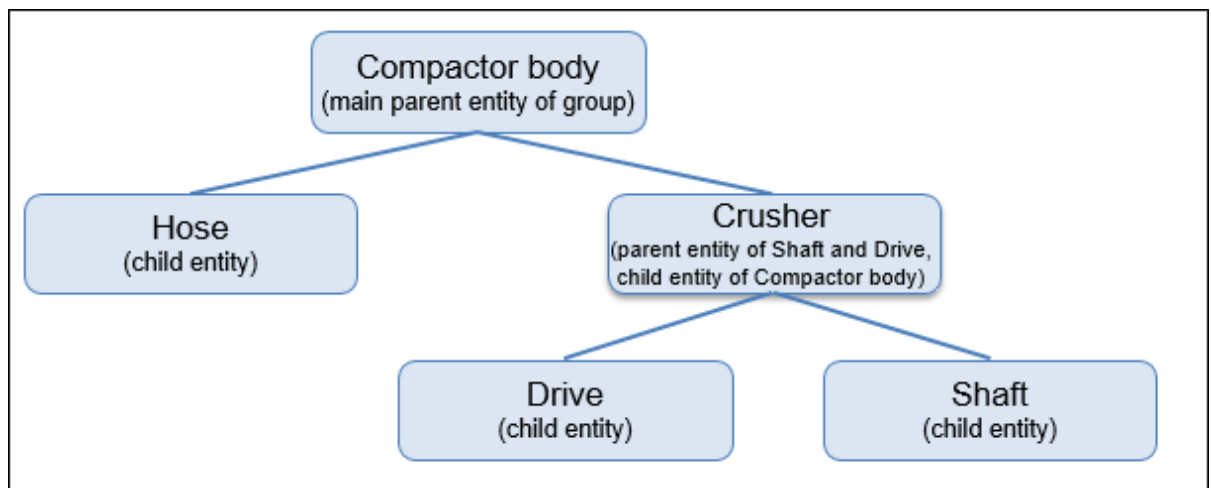


*Figure 3: Example configuration - group two equipment entities*
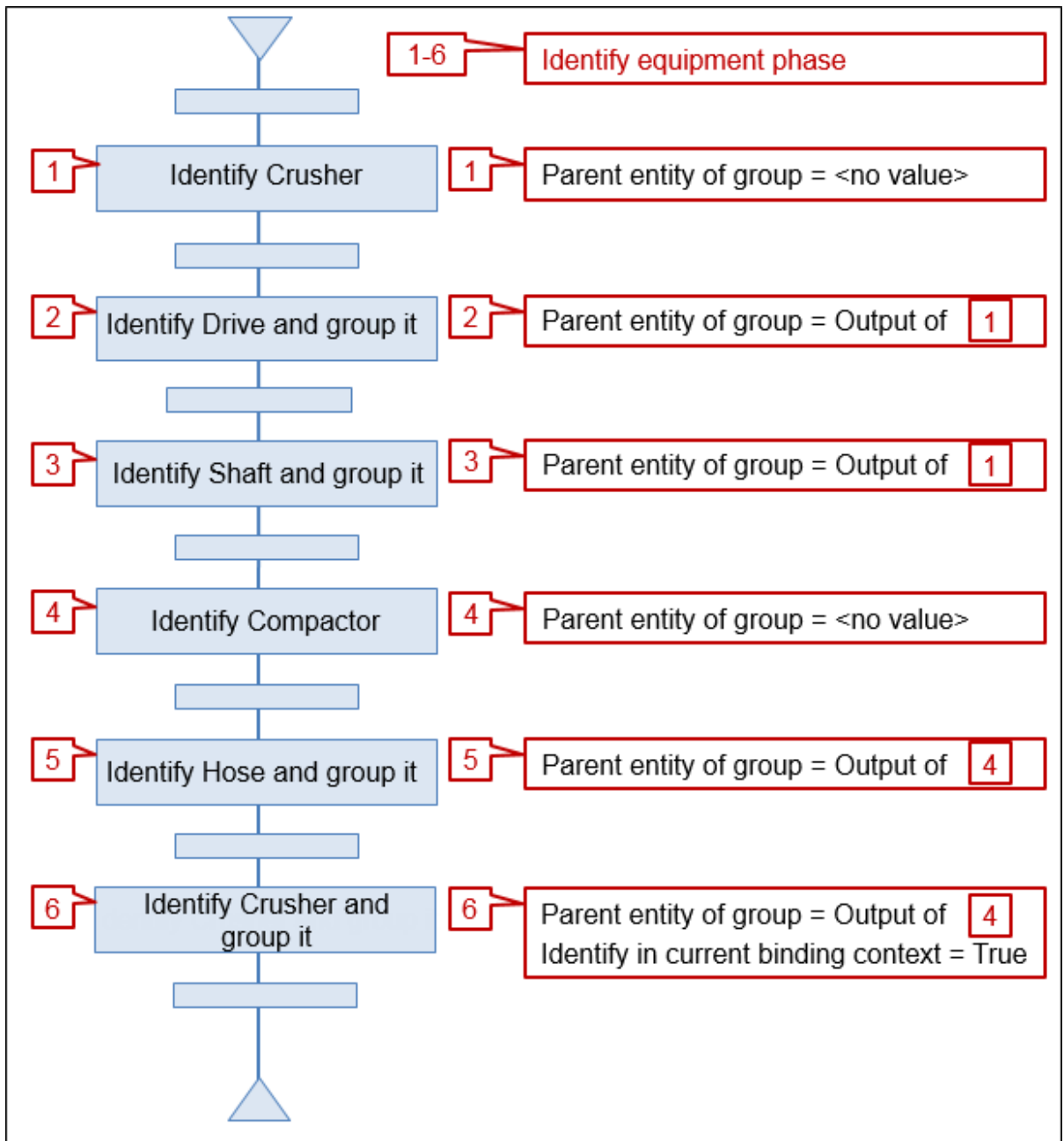
*Figure 4: Example configuration - group two equipment entities*

### 2.3.2 Identifying an Equipment Entity Group for Usage

To use an equipment entity group for production, e.g. a Compactor, the group must be identified with the **Identify equipment** phase.

For identifying of an equipment entity group for usage, the following configuration rules apply to the process parameters of the **Identify equipment** phase:

- Parent entity of group (GID-2671824) must not be set.

- Identify in current binding context (GID-2671825) must be set to **No**.

- Identification mode (GID-2671826)must be set to **Entity or group** (if the identification of an entity group is optional) or **Entity group required** (if only an entity group must be identified).

It is sufficient to identify any one entity of the group, its main parent entity or even any child entity, e.g. the Hose of the Compactor. After the successful identification, the **Identify equipment** phase determines the main parent entity as the identified entity, however, all of the entities of the group are bound to the current unit procedure context.

For a successful identification, all defined equipment requirement rules must be fulfilled. The child entities of the group are checked with the group-enabled conditional rules. Other equipment requirements are only checked against the main parent entity of the group. In addition, the equipment graph status values of all entities are checked and refreshed, if expired.

### 2.3.3 Re-identifying an Already Bound Equipment Entity or Group

The **Identify equipment** phase also supports the re-identification of an already bound equipment entity or entity group.

A typical use case during execution is the re-identification of an equipment entity in a different room, but within the same unit procedure. Another use case is the disassembling of a group (see "Separating an Equipment Entity Group" (GID-2669514)).

For re-identifying of an equipment entity or entity group, the following configuration rules apply to the process parameters of the **Identify equipment** phase:

- Parent entity of group (GID-2671824)must not be set.

- Identify in current binding context link must be set to **Yes**.

- Identification mode (GID-2671825)can be set to **Entity or group** (if both are allowed), **Single entity required** (if only a single entity must be identified), **Entity group required** (if only an entity group must be identified), or **Child entity (already bound)** (if the system shall not determine the related main parent entity, e.g., for separation).

### 2.3.4 Triggering a Graph Transition on an Equipment Entity Group

In order to support status transitions on many equipment entities that are assigned to a group, the **Trigger graph transition** phase performs the selected trigger on all entities of the group that hold an equipment graph of the configured purpose.

For triggering a graph transition on an equipment entity group, the following configuration rules apply to the process parameters of the **Trigger graph transition** phase:

- Identified equipment entity (GID-2671477)must reference the main parent entity of the group.

- Allowed triggers (GID-2671479)must be set to a purpose that at least one entity of the group holds.

Graphs with a different purpose are simply ignored. However, if none of the entities of the group holds a graph of the configured purpose, the result is a data mismatch system-triggered exception.

Depending on the graph configuration, the configured trigger may result in alternative status transitions, based on preconditions or different source statuses. For details, see "Functional Requirement Specification Data Management" [A3] (GID-2667997).
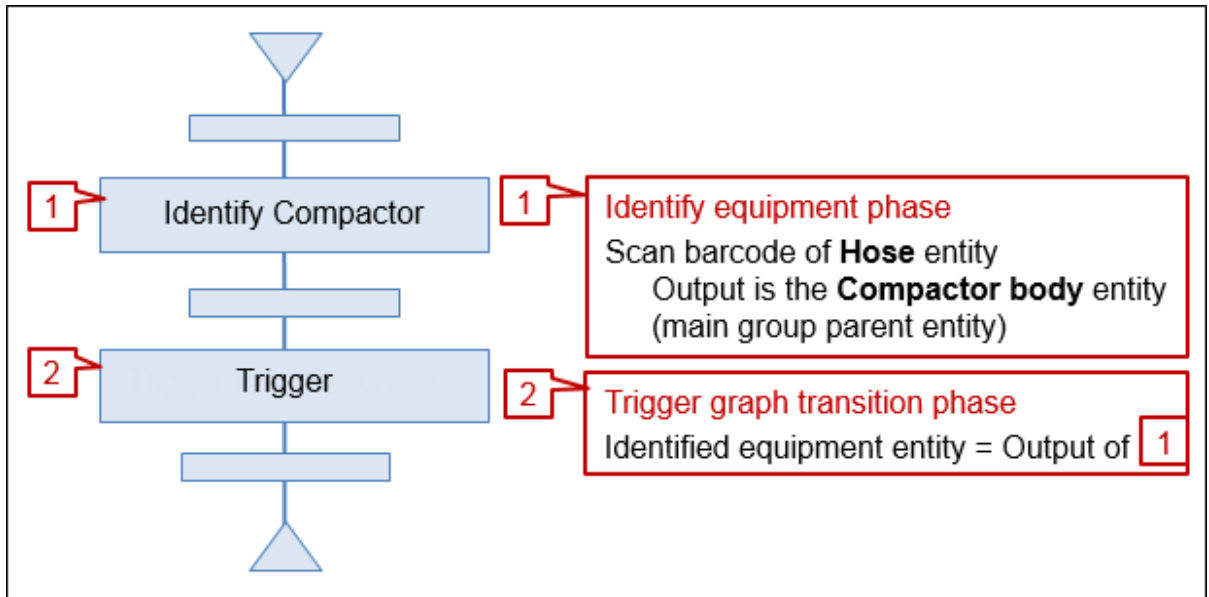


*Figure 5: Compactor - example configuration - trigger a graph transition*

### 2.3.5 Separating an Equipment Entity Group

In case of disassembly, the equipment entity or sub-group that has been disassembled physically also needs to be separated from the main group logically.
For this purpose, the **Separate equipment** phase supports the following key scenarios:

- Separating the entire group into all of its single entities, including the separation of all sub-groups (if applicable).

- Separating all child entities or sub-groups from the main parent entity, but keep all sub-groups (if applicable).

- Separating a specific child entity or sub-group from the main group (specific sub-group can be kept or completely separated, too).

In addition, the phase allows to configure if the separated entities or groups shall keep their binding status or shall be unbound from the current unit procedure.

For separating an equipment entity group, the following configuration rules apply to the process parameters of the **Separate equipment** phase (see also figure below):

- Parent entity of group (GID-2671500)must reference the main parent entity of the group.

- Child entity to be separated (GID-2671501)can reference the specific child entity or sub-group to be separated (see "Re-identifying an Already Bound Equipment Entity or Group" (GID-2669512)). If no entity is referenced (null), all child entities and sub-groups are separated from the main parent entity.

- Keep sub-group (GID-2671504)can be set to **Yes** (if separated sub-groups shall remain as a group) or **No**.

- Keep binding (GID-2671505)can be set to **Yes** (if separated entities shall keep their binding status) or **No**.
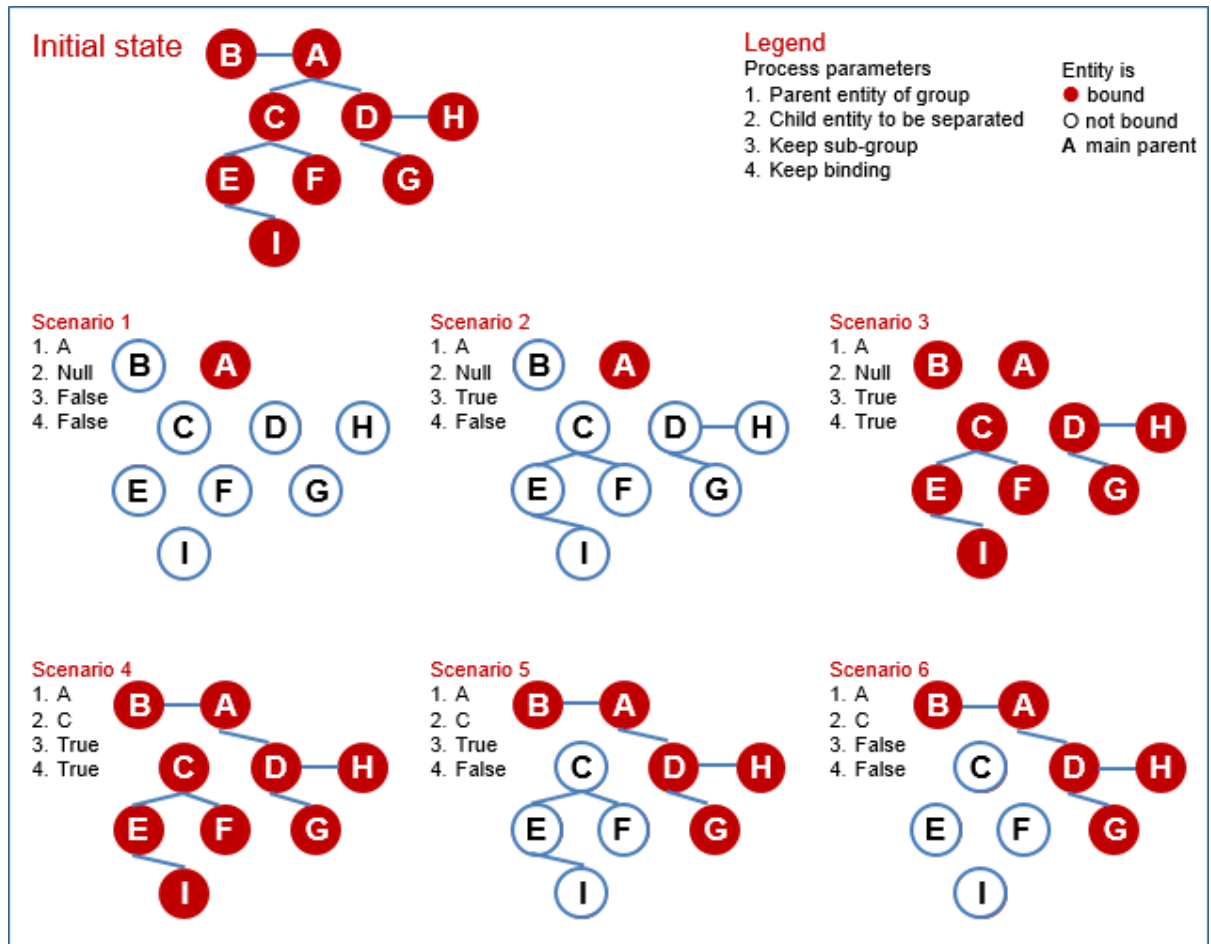


*Figure 6: Separate equipment scenarios*

The example configuration below shows a use case where a sub-group is separated from its main group and the sub-group remains as a group: The Compactor needs a special cleaning, but the Crusher of the Compactor can be reused unchanged with another compactor unit. For this reason, the Crusher sub-group shall be kept.

The Crusher and the Hose are separated from the Compactor body. The Drive and Shaft child entities remain grouped with the Crusher as their parent. All separated entities are unbound from the current unit procedure context.
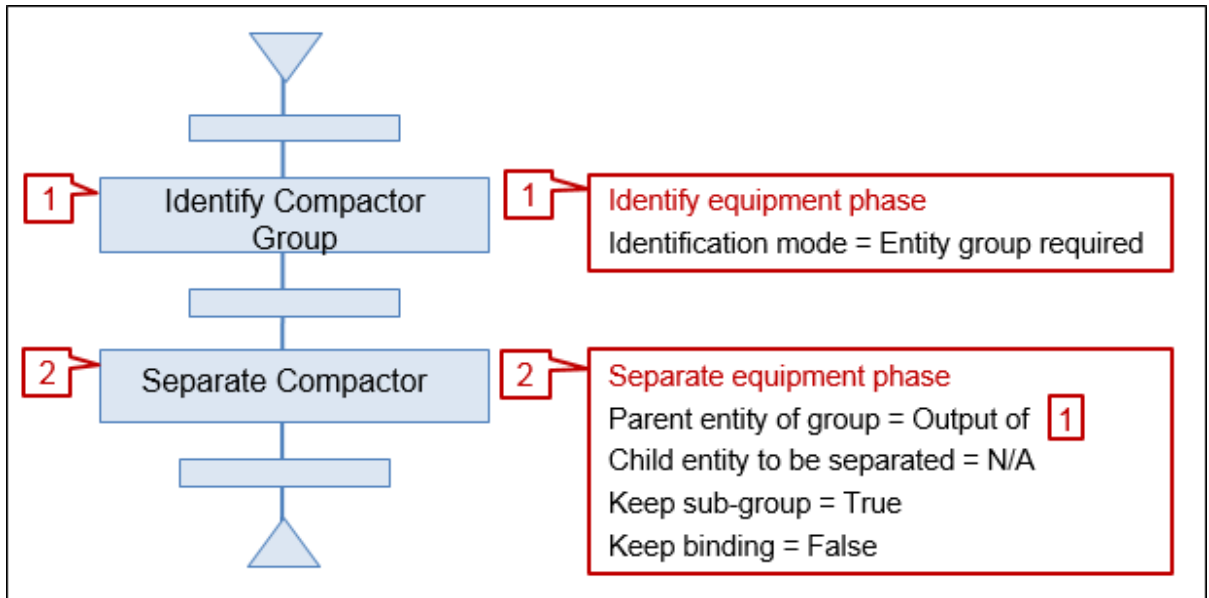
*Figure 7: Separate equipment scenarios*

The given example results in the following parent-child relations of the original Compactor.
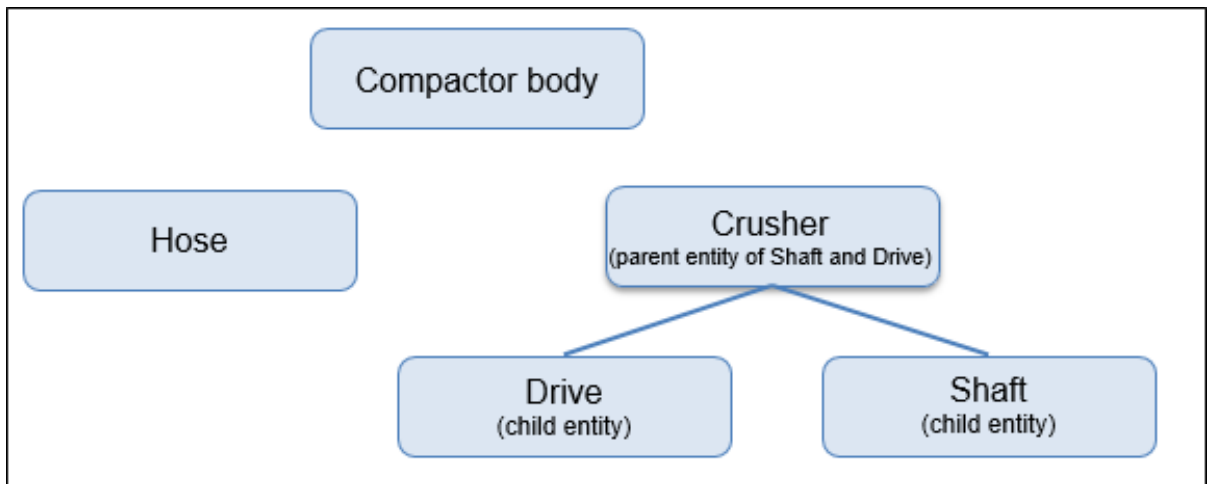


*Figure 8: Separate equipment scenarios*

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# 3 Identify Equipment Phase (SR0300+)

The **Identify equipment** phase allows to identify an equipment entity or an equipment entity group and to bind the entity to the context in which it is being used (e.g. order, workflow). Additionally, the phase allows to build an equipment entity group. As a prerequisite for binding, the phase performs fit-for-purpose checks. For verification purposes, an already bound equipment entity can be re-scanned within the same unit procedure context.

Example use cases are:

- Verifying that an equipment entity or an equipment entity group (parent entity and its child entities) meets requirements
  Equipment entities used during processing must meet various requirements. Prior to being used, an equipment entity is checked against the defined requirements (equipment class and additional properties). The ensuing results are documented in the entity's logbook.

- Exclusive usage of an equipment entity or equipment entity group for processing an order
  In order to ensure the exclusive usage of a specific equipment entity or equipment entity group, the entity or entity group (including all of its child entities) is bound to a batch and unit. The binding itself is documented in the batch report and the entity's logbook.

- Identification of parent and child equipment entities either for grouping equipment entities or for separating equipment entity groups.

The identified equipment entity, its equipment class, grouping details (if applicable), and the equipment property values are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669517).

Anomalies that occur during processing are covered by the phase exception handling (GID-2668273)(e.g. requirements are not met).

After completion the phase displays the identified equipment entity with the following data in the Execution Window:

- Required class identifier and short description
- Additional requirements (property and rule level)
- Parent entity for grouping (if applicable)
- Actual entity identifier and short description
- Statuses of the identified entity
- List of child entities (if applicable)

The Navigator displays the identifier of the identified equipment entity and the scanned equipment entity (if applicable).

**Scan a tableting unit label.**

| Required class | Additional requirements | Actual entity | Statuses |
|---|---|---|---|
| TabletPresses-A / Automated Tablet Presses | - Tablet Count / Tablet Count: ea | | |
| | | TabletPress_AM / Automated Tablet Press | - Unit Cleaning Graph / Clean |

Confirm

*Figure 9: Identify equipment during execution*

**Scan a tableting unit label.**

| Required class | Additional requirements | Actual entity | Statuses |
|---|---|---|---|
| TabletPresses-A / Automated Tablet Presses | - Tablet Count / Tablet Count: ea | | |
| | | TabletPress_AM / Automated Tablet Press | - Unit Cleaning Graph / Clean |

**List of child entities of TabletPress_AM / Automated Tablet Press**

| Identifier | Short description | Statuses |
|---|---|---|
| TabletDischargeChute | Discharge chute for Automated Tablet Press | - Unit Cleaning Graph / Clean |
| TabletPressFeeder | Feeder for Automated Tablet Press | - Unit Cleaning Graph / Clean |
| TabletPressFeederSeal | Feeder Seal for Automated Tablet Press | - Unit Cleaning Graph / Clean |

Confirm

*Figure 10: Identify equipment during execution*

**Scan a feeder label.**

**Parent entity for grouping: TabletPress_AM / Automated Tablet Press**

| Required class | Additional requirements | Actual entity | Statuses |
|---|---|---|---|
| TabletPresses-A / Automated Tablet Presses | - Rule-01 / Feeder group clean | | |
| | | TabletPressFeeder / Feeder for Automated Tablet Press | - Unit Cleaning Graph / Clean |

**List of child entities of TabletPressFeeder / Feeder for Automated Tablet Press**

| Identifier | Short description | Statuses |
|---|---|---|
| TabletPressFeederSeal | Feeder Seal for Automated Tablet Press | - Unit Cleaning Graph / Clean |

Confirm

*Figure 11: Identify equipment during execution*

*Figure 12: Identify equipment during execution*

## 3.1 Layout

The phase provides individual layouts for its representation during execution (GID-2669515), in the Navigator (GID-2669516), and in the sub-report (GID-2669517).

### 3.1.1 Representation during Execution (SR0300.1+)

The representation during execution depends on the phase mode.

#### 3.1.1.1 GID-2671406 PREVIEW MODE (SR0300.1.1)

1. \<Instruction text\>
   (taken from **Instruction (SR0300.8.1)** process parameter (GID-2671822))

2. Parent entity for grouping:

   ▪ Only if the **Parent entity of group (SR0300.8.6)** process parameter (GID-2671824)is not null.

3. Table with list of equipment requirements required for identification
   (taken from **Equipment parameters ( (GID-2671415))** process input link)

4. Empty list of property data (Table of property data (SR0300.1.4) link)

5. Empty list of child entities of the group

   ▪ Only if the **Show children ( (GID-2671827))** process parameter link is set to **Yes**.

6. **Confirm** button (disabled).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Medium |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.1.1.2 GID-2671407 ACTIVE MODE (SR0300.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0300.8.1)** process parameter (GID-2671822))

3. Parent entity for grouping: <parent entity identifier> / <parent entity short description, if applicable>

   ▪ Only if the **Parent entity of group (SR0300.8.6)** process parameter (GID-2671824)is not null.

4. Table with list of equipment requirements required for identification
   (taken from **Equipment parameters (SR0300.6.1)** process input (GID-2671415))

   ▪ Required class

   ▪ Additional requirements [rule identifier / description or rule expression (if description is empty)]
     (This is related to properties, property values, and flexible rules.)

     ▪ Actual entity (identified equipment)

     ▪ If an entity group has been identified, the actual entity is the main parent entity of the group, which may not be the entity that was scanned.

     ▪ Statuses (all actual statuses (available in the used FSM or graph) of the identified entity)

5. List of property data (Table of property data (SR0300.1.4) (GID-2671409))

6. List of child entities of the group <actual entity identifier> / <actual entity short description, if applicable>

   ▪ Only if an entity group has been identified and the **Show children (SR0300.8.9)** process parameter (GID-2671827)is set to **Yes**.

   ▪ Details of child entity.

| <Child entity identifier> | <Child entity short description> | <Entity graph status> |
|---|---|---|

7. **Confirm** button.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.1.1.3 GID-2671408 COMPLETED MODE (SR0300.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0300.8.1)** process parameter (GID-2671822))

3. Parent entity for grouping: <parent entity identifier> / <parent entity short description, if applicable>

   ▪ Only if the **Parent entity of group (SR0300.8.6)** process parameter (GID-2671824)is not null.

4. Table with list of equipment requirements required for identification
   (taken from **Equipment parameters (SR0300.6.1)** process input (GID-2671415))

5. List of child entities of the group <actual entity identifier> / <actual entity short description, if applicable>

   ▪ Only if an entity group has been identified and the **Show children (SR0300.8.9)** process parameter (GID-2671827)is set to **Yes**.

   ▪ Details of child entity.

| <Child entity identifier> | <Child entity short description> | <Entity graph status> |
|---|---|---|

6. List of property data (Table of property data (SR0300.1.4) (GID-2671409))

7. **Confirm** button (completed).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.1.1.4 GID-2671409 TABLE OF PROPERTY DATA (SR0300.1.4)

Only if an **Equipment property list (SR0300.8.12)** bundle process parameter (GID-2671828)is defined.

For all entities of the identified equipment or equipment group that match an **Equipment property list (SR0300.8.12)** bundle process parameter definition for an entity, the following data is displayed:

| <Entity [identifier]> | <Property [identifier]> | <[Property ] Value> |
|---|---|---|

The table is sorted first by entity identifier, secondly by property identifier.

If the **Equipment property list (SR0300.8.12)** bundle process parameter definition contains an equipment class definition, the entity with this attribute is only displayed if the entity is assigned to the defined equipment class.

If the property or equipment graph defined as attribute is not available at the entity, the table entry is omitted and not displayed.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.1.2  Representation in Navigator (SR0300.4+)

The Navigator provides the following details:

#### 3.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- \<Phase name>

    - Example:
      Identify mixer

#### 3.1.2.2 GID-2671411 INFORMATION COLUMN (SR0300.4.1)

- \<Identifier of identified equipment entity>

    - Example: 23480Compactor

    - If an entity group has been identified:

    - \<Identifier of identified equipment entity (main parent>)
      \<Identifier of the scanned entity>

        - Example:
          23480Compactor
          23478Frame

    - If the identification has been skipped, no data is displayed.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Low |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 3.1.2.3 ACTION COLUMN

- There are no actions available.

### *3.1.3  Representation in Sub-report (SR0300.5+)*

The sub-report contains the following information:

#### 3.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>

- <Completion time>

- <Unit procedure> / <operation> / <phase>

- <Work center> / <station> / <device> - <phase completion user>

#### 3.1.3.2 GID-2671414 SUB-REPORT ELEMENTS (SR0300.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Instruction text

- Parent entity for grouping: <parent entity identifier> / <parent entity short description>

  - Only if the **Parent entity of group (SR0300.8.6)** process parameter (GID-2671824)is not null.

  - Required equipment class (identifier and short description)

  - Identified equipment entity (identifier and short description)

    - Represents the main parent entity if an entity group has been identified.

  - Scanned equipment entity (identifier and short description)

    - Only if an entity group has been identified.

  - Additional requirements [rule identifier / description or rule (if description is empty)]

  - Actual property names and values (for additional non-status property type-based requirements of the identified equipment) and all status values (available in the used FSM or graph) of the identified equipment entity (e.g. cleaning status)

    - If an equipment entity group has been identified, data of the parent entity is shown.

    - For properties of the **Automation** type, the value is always N/A.

  - List of property data (Table of property data (SR0300.1.4) (GID-2671409))

  - Child equipment entities (identifier and short description)

  - All status values (available in the used graph) of child equipment entities (e.g. cleaning status)

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 3.2 Business Logic (SR0300.2+)

The phase implements the following business logic.

### 3.2.1 GID-2669518 Identify and bind equipment entity (SR0300.2.1)

Function: Identify equipment entity or equipment entity group

Trigger: Phase becomes active

Postcondition: Equipment entity or entity group is identified

| Step | # | Description |
|------|---|-------------|
| Phase activation | 10 | Phase displays its user interface according to the **Active mode (SR0300.1.2)** layout (GID-2671407). |
| Operator scans barcode | 20 | The **Scan equipment entity barcode (SR0300.2.2)** function (GID-2669519) becomes active.<br>For manual identification, see **Enter identifier manually (SR0300.3.1.1)** user-triggered exception (GID-2671422). |
| Phase performs pre-identification checks | 30 | The **Identify equipment entity (SR0300.2.3)** function (GID-2669520)becomes active. |
| Phase performs pre-binding checks | 40 | The **Bind equipment entity (SR0300.2.4)** function (GID-2669521)becomes active. |
| Operator confirms phase | 50 | ▪ If no equipment entity or entity group has been identified successfully, phase displays the **Nothing identified (SR0300.3.6.5)** error message (GID-2671430). The phase cannot be completed.<br>▪ If the checks have passed successfully and an equipment entity or entity group is bound, the operator confirms the identification of the equipment entity or entity group.<br>▪ Phase sets the **Result (SR0300.9.4)** output variable (GID-2669537)to IDENTIFIED.<br>▪ Phase is completed. |
| Phase runs in **Automatic completion** mode | 60 | In case the entity or entity group has been identified and is bound without any exceptions and the **Mode (SR0300.8.10)** process parameter link is set to **Automatic completion**, phase sets the **Result (SR0300.9.4)** output variable (GID-2669537)to IDENTIFIED and is completed automatically. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.2.2  GID-2669519 Scan equipment entity barcode (SR0300.2.2)

- Function: Scan an equipment entity barcode

- Trigger: Operator scans barcode

- Postcondition: Equipment entity barcode is scanned

| Step | # | Description |
|---|---|---|
| Operator scans barcode | 10 | Phase reads scanned data. |
| Phase performs checks | 20 | <ul><li>If barcode reading was technically successful, phase updates background color of phase representation according to style sheet in order to confirm the reading.</li><li>If barcode reading was technically not successful, phase remains in listening mode.</li><li>If barcode reading was not successful, phase displays the **Cannot find entity (SR0300.3.6.1)** error message (GID-2669528)</li></ul> |
| | | If the checks have passed successfully, phase continues with the **Identify and bind equipment entity (SR0300.2.1)** function (GID-2669518). |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.2.3  GID-2669520 Identify equipment entity (SR0300.2.3)

- Function: Identify a scanned equipment entity or equipment entity group

- Trigger: Equipment entity is scanned successfully

- Postcondition: Equipment entity or entity group is identified

| Step | # | Description |
|------|-----|-------------|
| Phase checks identification mode | 05 | ▪ If the **Identification mode (SR0300.8.8)** process parameter (GID-2671826)is set to **Entity group required**, but the scanned entity is not member of an entity group:<br>Phase displays the **Entity is not part of a group (SR0300.3.6.11)** error message (GID-2671433).<br><br>▪ If the **Identification mode (SR0300.8.8)** process parameter (GID-2671826)is set to **Single entity required**, but the scanned entity is member of a group:<br>Phase displays the **Entity is part of a group (SR0300.3.6.10)** error message (GID-2671432).<br><br>▪ If the **Identification mode (SR0300.8.8)** process parameter (GID-2671826)is set to **Child entity (already bound)**, but one of the following items applies:<br>the **Parent entity of group (SR0300.8.6)** process parameter (GID-2671824)is not null,<br>or<br>the entity is not member of a group,<br>or<br>the entity is a main parent,<br>or<br>the **Identify in current binding context (SR0300.8.7)** process parameter (GID-2671825)is not set to **Yes**:<br>Phase displays the **Not a child entity of bound group (SR0300.3.6.13)** error message (GID-2671435). |
| Phase determines main parent entity | 10 | If the scanned equipment entity is member of a group, phase determines, for the scanned entity, the main parent entity of its group and all child entities that belong to the same group. |
| Phase checks availability of equipment entity | 15 | The following checks either apply to a single entity or to a main parent entity and to all of its child entities, respectively:<br><br>▪ If the **Identify in current binding context (SR0300.8.7)** process parameter (GID-2671825)is set to **Yes**, phase expects and only allows entities that are already bound to the current unit procedure context. If the identification is done in a workflow that is appended to a unit procedure of an order, the phase also allows the entities that are bound to the unit procedure context of this order. In case an entity is not already bound to an allowed unit procedure context:<br>Phase displays the **Not available for usage (SR0300.3.6.4)** error message (GID-2671429).<br><br>▪ If the **Identify in current binding context (SR0300.8.7)** process parameter is set to **No**, phase expects an unbound entity. In case an entity has already been identified or bound in the context of a different phase or even order:<br>Phase displays the **Not available for usage (SR0300.3.6.4)** error message (GID-2671429). |

| Step | # | Description |
|---|---|---|
| | 20 | The following checks either apply to a single entity or to a main parent entity (not to all child entities of a group):<br><br>▪ If the entity has already been identified in the context of this phase:<br>Phase displays the **Already identified (SR0300.3.6.2)** error message (GID-2669529).<br><br>▪ Only if the phase has been resumed and the entity has already been identified in the context of this phase:<br>Phase continues with the **Bind identified equipment entity (SR0300.2.4)** function (GID-2669521). |
| Phase performs grouping-related checks | 25 | The following check applies if the **Parent entity of group (SR0300.8.6)** process parameter link is not null:<br><br>▪ If the **Parent entity of group (SR0300.8.6)** process parameter (GID-2671824)is not null, but the referenced entity is not bound to the current unit procedure context:<br>Phase displays the **Parent entity not bound (SR0300.3.6.14)** error message (GID-2671436).<br><br>▪ If the identified entity to be added to the group is the same as the pre-defined parent entity of the group according to the **Parent entity of group (SR0300.8.6)** process parameter (GID-2671824):<br>Phase displays the **Group cycle error (SR0300.3.6.12)** error message (GID-2671434). |
| Phase sets binding status to **Identified** | 30 | If all checks pass successfully, the following logic either applies to a single entity or to a main parent entity and to all of its child entities, respectively:<br><br>▪ If the **Identify in current binding context (SR0300.8.7)** process parameter (GID-2671825)is set to **Yes**:<br>Phase does not update the binding status because the equipment entity is already bound to a unit procedure context. Phase updates the logbook with the additional identification (if maintained).<br><br>▪ If the **Identify in current binding context (SR0300.8.7)** process parameter (GID-2671825)is set to **No**:<br>Phase changes the binding status of the equipment entity to **Identified**, updates the logbook accordingly (if maintained), and continues with the **Bind identified equipment entity (SR0300.2.4)** function (GID-2669521). |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.2.4 GID-2669521 Bind identified equipment entity (SR0300.2.4)

- Function: Bind an identified equipment entity or equipment entity group

- Trigger: Equipment entity or entity group is identified successfully

- Postcondition: Equipment entity or entity group is bound

| Step | # | Description |
|------|---|-------------|
| Phase checks if graph statuses are expired | 5 | Only if the **Identify in current binding context (SR0300.8.7)** process parameter (GID-2671825)is set to **No**:<br>The **Refresh expired equipment status (SR0300.2.5)** function (GID-2669522)becomes active. |
| Phase checks class membership of equipment entity | 10 | The following check either applies to a single entity or to a main parent entity (not to child entities of a group). However, the resulting action applies to all entities of an entity group (if applicable):<br><br>- If the identified entity is not member of the required class, phase resets the binding status of the equipment entity (all entities of the entity group) to **Available**, updates the logbook accordingly (if maintained), and displays the **Not member of required class (SR0300.3.6.3)** error message (GID-2671428)<br>- If the check passes successfully, phase continues with the next check. |
| Phase checks if class and entity fulfill the minimum required status | 15 | The following check either applies to a single entity and its required class, or, in case of an entity group, to the main parent entity and its required class and to all child entities, respectively.<br><br>In addition, it applies to all classes that are explicitly defined as an equipment requirement with a conditional rule and the **equipmentIsMemberOfClass** function. For details, see **Expressions for Conditional Rules (SR3146.9.9.4.12)** and **Expression Editor – Runtime Context Data (SR3146.9.9.6)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2667997).<br><br>- Phase checks for the minimum class status and the minimum entity status according to the **Equipment status check (SR0300.8.5)** process parameter link. If the check fails, phase creates the **Equipment status check (SR0300.3.2.2)** system-triggered exception (GID-2671837).<br>- If the check passes successfully, phase continues with the next check. |

| Step | # | Description |
|---|---|---|
| Phase checks if property values of equipment entity match and if rules are fulfilled | 20 | The following checks either apply to a single entity or to a main parent entity (not to child entities of a group):<br><br>▪ If any of the property value-related or flexible rule-related checks fail, phase creates the **Property value check (SR0300.3.2.1)** system-triggered exception (GID-2671421).<br><br>The following check either applies to a single entity or to a main parent entity and to all of its child entities, respectively:<br><br>▪ If the group-enabled conditional rule-related check fails, phase creates the **Property value check (SR0300.3.2.1)** system-triggered exception (GID-2671421). |
| Phase sets binding status to **Bound** | 30 | If all checks pass successfully or the exception is recorded, the following logic either applies to a single entity or to a main parent entity and to all of its child entities, respectively:<br><br>▪ If the **Identify in current binding context (SR0300.8.7)** process parameter (GID-2671825) is set to **Yes**:<br>Phase does not update the binding status because the equipment entity is already bound to a unit procedure context.<br><br>▪ If the **Identify in current binding context (SR0300.8.7)** process parameter (GID-2671825) is set to **No**:<br>Phase sets the status of the equipment entity to **Bound** and updates the binding context in the **Context** tab of the equipment entity (not for workflows) and the logbook accordingly (if maintained). |
| Phase performs group assignment | 40 | The following logic either applies to a single entity or to a main parent entity (not to child entities of a group):<br><br>▪ If the **Parent entity of group (SR0300.8.6)** process parameter (GID-2671824) is not null:<br>Phase assigns the identified equipment entity as new child entity to the pre-defined parent entity of the group according to the **Parent entity of group (SR0300.8.6)** process parameter (GID-2671824).<br><br>(In case the identified equipment entity has been a main parent entity, it now becomes a sub-parent entity.) |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.2.5  GID-2669522 Refresh expired equipment status (SR0300.2.5)

▪ Function: Refresh the expired statuses of an equipment entity or equipment entity group

▪ Trigger: Equipment entity or entity group is identified successfully

▪ Postcondition: Expired equipment graph statuses of entity or entity group are updated

| Step | # | Description |
|---|---|---|
| Phase checks if graph statuses are expired | 10 | The following logic either applies to a single entity or to a main parent entity and to all of its child entities, respectively:<br><br>Phase checks in a loop for all equipment graphs assigned to the entity if the current status of equipment graph has expired.<br><br>▪ If the status is **not expired**, phase checks the next equipment graph.<br><br>▪ If the status is **expired**, phase performs the **Expired (RS)** equipment graph trigger and checks the next equipment graph. |
| | 20 | The following logic either applies to a single entity or to a main parent entity and to all of its child entities, respectively:<br><br>If the execution of any **Expired (RS)** equipment graph trigger fails, phase resets the binding status of the equipment entity to **Available**, updates the logbook accordingly (if maintained), and displays the **Expired trigger execution failed (SR0300.3.6.9)** error message (GID-2671431). |
| | 30 | If the execution of all **Expired (RS)** equipment graph trigger passed successfully, the phase continues with further checks of the **Bind identified equipment entity (SR0300.2.4)** function (GID-2669521). |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 3.3 Phase Parameters

The phase provides equipment parameters as process inputs (GID-2669523) and process parameters (GID-2669524).

### 3.3.1 Process Inputs (SR0300.6+)

#### 3.3.1.1 GID-2671415 EQUIPMENT PARAMETERS (SR0300.6.1)

Equipment parameters allow to define an equipment requirement as follows:

▪ by assigning an equipment class and

  ▪ by assigning a specific property type (check against existence),

  ▪ by setting specific property values (check against value, see **Technical Property Types and Editors (SR3071.8.7+)** in "Functional Requirement Specification Data Management" [A3] (GID-2667997),

  ▪ by defining a flexible rule, or

  ▪ by defining a conditional rule.

For properties of the following data types, the property values cannot be accessed within rules:

- Equipment type
- Flexible tag definition
- Ranges
- Room cleaning rules
- Scale configuration
- Work center assignment

For details about rules, see **Expressions for Flexible Rules (SR3146.9.9.4.10)** and **Expressions for Conditional Rules (SR3146.9.9.4.12)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2667997).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.3.2  Process Parameters (SR0300.8+)

The following process parameters define the behavior of the phase.

#### 3.3.2.1 INSTRUCTION TABLE-SPECIFIC PARAMETERS

##### 3.3.2.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Table layout | Choice list | Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**. |
| First column narrow | Boolean | Defines if the first column of the table shall be narrow. |
| Show all borders | Boolean | Defines if the borders of the table shall be visible. |

3.3.2.1.2   INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Column 1 | HTML text | Instruction text to be displayed in a column.<br>**Restriction**: Maximum length is 2000 characters (including HTML tags). |
| Column 2 | HTML text | |
| Column 3 | HTML text | |
| Column 4 | HTML text | |
| Column 5 | HTML text | |

### 3.3.2.2 INSTRUCTION LINK-SPECIFIC PARAMETERS

3.3.2.2.1   INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Instruction text | HTML text | Instruction text to be displayed.<br>For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671821).<br>Example: Refer to {SOP1270} for guidance.<br><br>Maximum length is 2000 characters (including HTML tags). |

3.3.2.2.2   INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Link text | Text | Text to be used as link.<br>For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute.<br>Including the brackets in the link text is optional.<br><br>Maximum length is 80 characters. |

| Attribute | Type | Comment |
|---|---|---|
| Link URL | Text | URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system.<br><br>Maximum length is 256 characters. |

### 3.3.2.3 BASIC PARAMETERS

3.3.2.3.1  GID-2671822 INSTRUCTION (SR0300.8.1)

| Attribute | Type | Comment |
|---|---|---|
| Text | HTML text | Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags). |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

3.3.2.3.2  GID-2671823 MODE (SR0300.8.10)

| Attribute | Type | Comment |
|---|---|---|
| Mode | Choice list | Defines the processing mode. **Manual completion (default)**: Operator confirms phase manually. **Automatic completion**: Phase is completed automatically when the identified entity or entity group is bound without any exceptions. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.3.2.3.3 GID-2671824 PARENT ENTITY OF GROUP (SR0300.8.6)

| Attribute | Type | Comment |
|---|---|---|
| Equipment object | Reference | Reference to the equipment object output variable of a preceding phase that defines the parent entity of the group.<br>The identified equipment entity is added to the parent entity as a child entity. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.3.2.3.4 GID-2671825 IDENTIFY IN CURRENT BINDING CONTEXT (SR0300.8.7)

| Attribute | Type | Comment |
|---|---|---|
| Enabled | Boolean | Controls if the identification is only possible if the entity or entity group is already bound to an allowed unit procedure context. If the identification is done in a workflow that is appended to a unit procedure of an order, the phase also allows the entities that are bound to the unit procedure context of this order.<br>Default setting: **No** |

By configuration, it is possible to restrict the allowed unit procedure context for identification to the unit procedure of the phase in order to support behavior as prior to PharmaSuite 9.2.

> For configuration details on the **IdentifyAlreadyBoundEqmFromAppendedWorkflow** key, see chapter "Configuration Keys of PharmaSuite" in Volume 4 of the "Technical Manual Configuration and Extension" [A4] (GID-2667997).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.3.2.3.5 GID-2671826 IDENTIFICATION MODE (SR0300.8.8)

| Attribute | Type | Comment |
|-----------|------|---------|
| Enabled | Choice list | Defines the identification mode. Available settings: **Entity or group**, **Single entity required**, **Entity group required**, **Child entity (already bound)**. Default setting: **Entity or group**. |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.3.2.3.6 GID-2671827 SHOW CHILDREN (SR0300.8.9)

| Attribute | Type | Comment |
|-----------|------|---------|
| Enabled | Boolean | Controls if the list of child entities is displayed during execution. Default setting: **Yes** |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.3.2.3.7 GID-2671828 EQUIPMENT PROPERTY LIST (SR0300.8.12)

The phase allows up to ten bundle process parameters of this type.

| Attribute | Type | Comment |
|-----------|------|---------|
| Equipment class | Equipment class object | Optional. Prefilled with the last value used. If defined, an attribute of the identified equipment entity is only then displayed during execution if the entity is assigned to this equipment class. |
| Attribute | String | Property type or equipment graph whose data shall be displayed. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.3.2.3.8 EQUIPMENT CLASS SELECTION EDITOR (FRAMEWORK CAPABILITY)

The system provides an Equipment Class Selection editor for selecting an equipment class from the Universe. Equipment classes in a **Retired** state (e.g. Archived) are not available for selection.

### 3.3.2.3.9 ATTRIBUTE SELECTION EDITOR (FRAMEWORK CAPABILITY)

The system provides an Attribute Selection editor for selecting a property type or an equipment graph property (status or expiry date).

If an equipment class has been defined with the Equipment Class Selection editor of the process parameter, only properties of the selected equipment class are displayed.

### 3.3.2.4 CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

#### 3.3.2.4.1 GID-2671831 PROPERTY VALUE CHECK (SR0300.8.2)

| Attribute | Type | Comment |
|---|---|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.<br>Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**.<br>Default setting: **High**. |
| Exception text | Text | Defines the exception description used during exception handling and within the batch record.<br>Maximum length is 250 characters. |

See also **Property value check (SR0300.3.2.1)** system-triggered exception (GID-2671421).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.3.2.4.2 GID-2671832 EQUIPMENT STATUS CHECK (SR0300.8.5)

| Attribute | Type | Comment |
|---|---|---|
| Minimum class status | Choice list | Defines the minimum class status required for equipment identification. Available settings: **Verification**, **Approved.** Default setting: **Approved.** |
| Minimum entity status | Choice list | Defines the minimum entity status required for equipment identification. Available settings: **Verification**, **Approved.** Default setting: **Approved.** |
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).** Default setting: **High.** |
| Exception text | Text | Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters. |

See also **Equipment status check (SR0300.3.2.2)** system-triggered exception. (GID-2671837)

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.3.2.5 CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

#### 3.3.2.5.1 GID-2671833 ENTER IDENTIFIER MANUALLY (SR0300.8.3)

| Attribute | Type | Comment |
|---|---|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**. |
| Exception text | Text | Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters. |

> See also **Enter identifier manually (SR0300.3.2.1)** user-triggered exception (GID-2671421).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 3.3.2.5.2 GID-2671834 UNDO IDENTIFICATION (SR0300.8.4)

| Attribute | Type | Comment |
|---|---|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**. |
| Exception text | Text | Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters. |

> See also **Undo identification (SR0300.3.1.2)** user-triggered exception (GID-2671424).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.3.2.5.3  GID-2671835 Sᴋɪᴘ ɪᴅᴇɴᴛɪꜰɪᴄᴀᴛɪᴏɴ (SR0300.8.11)

| Attribute | Type | Comment |
|---|---|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.<br>Available settings: **None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).**<br>Default setting: **High.** |
| Exception text | Text | Defines the exception description used during exception handling and within the batch record.<br>Maximum length is 250 characters. |

> See also **Skip identification (SR0300.3.1.3)** user-triggered exception (GID-2671426).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 3.4  Exceptions (SR0300.3+)

The phase supports user-defined, user-triggered (GID-2669526), system-triggered (GID-2669525), and post-completion exceptions (GID-2668277) and their configuration by means of process parameters (GID-2669524).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

### 3.4.1  System-triggered Exceptions (SR0300.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

### 3.4.1.1 GID-2671421 PROPERTY VALUE CHECK (SR0300.3.2.1)

For each property that does not match, the exception lists the related rule identifier, the rule description (or the rule content, if the description is not maintained), the property identifier, and the expected and actual values.
For each flexible rule that is not fulfilled, the exception lists the related rule identifier, the rule description (or the rule expression, if the description is not maintained), and the expected and actual values of the expression.
For each conditional rule that is not fulfilled, the exception lists the related entity, the rule identifier, the rule description (or the rule expression, if the description is not maintained), and the expected and actual values of the expression.

Representation of the exception:

Exception dialog

- <Exception text>
  (taken from **Property value check (SR0300.8.2)** process parameter (GID-2671831))
  Cannot identify the <Identifier of identified equipment entity> entity, since it does not meet the defined equipment requirements.

Exception Window

- <Exception text>
  (taken from **Property value check (SR0300.8.2)** process parameter (GID-2671831))
  Cannot identify the <Identifier of identified equipment entity> entity, since it does not meet the defined equipment requirements.

  Rule: <identifier>
  Description: <rule description> (or <rule content/expression>, if the description is not maintained)

  - For properties that do not match:
    Equipment property: <identifier>
    Expected value: <value>
    Actual value: <value>

  - For flexible rules that are not fulfilled:
    Expected value: Yes
    Actual value: No

  - For conditional rules that are not fulfilled, same rule can apply to multiple entities:
    Entities: <identifier of entity 1 to which the rule applies>, ..., <identifier of entity n>
    Expected value: Yes
    Actual value: No

  - Example:
    Equipment requirement violation
    Cannot identify the AX67 entity, since it does not meet the defined equipment requirements.

Rule: Rule_01
Description: Check of cleaning status
Equipment property: Cleaning status
Expected value: Clean
Actual value: To be cleaned

Rule: Rule_02
Description: Required volume range
Equipment property: Volume
Expected value: 150 - 200 l
Actual value: 100 l

Rule: Rule_03
Description: Counter less or equal 5
Entities: Filter005
Expected value: Yes
Actual value: No

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 3.4.1.1.1 GID-2671836 PROPERTY VALUE CHECK - LOGIC (SR0300.3.2.1.1)

- Trigger: Check has failed

- Postcondition: Exception is recorded

| Step | # | Description |
|---|---|---|
| Operator accepts exceptional situation | 1-10 | Phase shows exception description to be signed. |
| Operator signs exception | 1-20 | Phase records the exception. |
| Operator does not accept exceptional situation | 2-10 | The following logic either applies to a single entity or to a main parent entity and to all of its child entities, respectively:<br>Phase resets status of equipment entity to **Available** and updates the logbook accordingly (if maintained). |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 3.4.1.1.2 GID-2671837 EQUIPMENT STATUS CHECK (SR0300.3.2.2)

The phase checks if the defined minimum statuses for the equipment class and entity are fulfilled according to the **Equipment status check (SR0300.8.5)** process parameter (GID-2671832).
The check either applies to a single entity and its required class, or, in case of an entity group, to the main parent entity and its required class and to all child entities, respectively.
In addition, the check applies to all classes (incl. classes of child entities) that are explicitly defined as an equipment requirement with a conditional rule and the **equipmentIsMemberOfClass** function. For details, see **Expressions for Conditional Rules (SR3146.9.9.4.12)** and **Expression Editor - Runtime Context Data (SR3146.9.9.6)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2667997).

Representation of the exception:

Exception dialog

- <Exception text>
  (taken from **Equipment status check (SR0300.8.5)** process parameter (GID-2671832))

  - If class status does not match:
    Cannot identify the <entity identifier > equipment entity, since its required class (<class identifier>) is in the <status> status.

  - If entity status does not match:
    Cannot identify the <identifier> equipment entity, since it is in the <status> status.

Exception Window

- <Exception text>
  (taken from **Equipment status check (SR0300.8.5)** process parameter (GID-2671832))

  - If class status does not match:
    Cannot identify the <entity identifier > equipment entity, since its required class (<class identifier>) is in the <status> status.
    Required minimum status: <status>

  - If entity status does not match:
    Cannot identify the <identifier> equipment entity, since it is in the <status> status.
    Required minimum status: <status>

  - Example:
    Equipment status violation
    Cannot identify the AX67 equipment entity, since its required class (CX14) is in the Verification status.
    Required minimum status: Approved

Cannot identify the AX67 equipment entity, since it is in the Draft status.

Required minimum status: Approved

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 3.4.1.1.3  GID-2671838 EQUIPMENT STATUS CHECK - LOGIC (SR0300.3.2.2.1)

- Trigger: Check has failed

- Postcondition: Exception is recorded

| Step | # | Description |
|---|---|---|
| Operator accepts exceptional situation | 1-10 | Phase shows exception description to be signed. |
| Operator signs exception | 1-20 | Phase records the exception. |
| Operator does not accept exceptional situation | 2-10 | The following logic either applies to a single entity or to a main parent entity and to all of its child entities, respectively: Phase resets status of equipment entity to **Available** and updates the logbook accordingly (if maintained). |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 3.4.1.1.4  GID-2671839 MULTIPLE FAILED CHECKS (SR0300.3.2.3)

In case multiple system-triggered exceptions occur, only one combined exception (system-triggered exception) is recorded including information about all exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

After the exception has been recorded, the phase must be manually completed.

Representation in the message dialog:

1. Several exceptions have occurred.
   For details navigate to the Exception Window.

2. **Exception** button

Representation during exception handling:

1. Exception text:
   <Concatenation of multiple exception texts>.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 3.4.2 User-triggered Exceptions (SR0300.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

#### 3.4.2.1 GID-2671422 ENTER IDENTIFIER MANUALLY (SR0300.3.1.1)

The **Enter identifier manually** exception allows an operator to enter the barcode of an equipment entity manually.

The exception is disabled, if the required equipment entity is already in the **Identified** or **Bound** status.

Representation during exception handling:

- Instruction:
  Identify by typing the entity barcode.
  Box for identifier input.
  **Confirm** button.

- Exception text:
  <Exception text>
  (taken from **Enter identifier manually (SR0300.8.3)** process parameter (GID-2671833))
  Manual entry: <barcode string>

  - Example:
    Equipment entity barcode entered manually
    Manual entry: 23478asUi

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

#### 3.4.2.2 GID-2671423 ENTER IDENTIFIER MANUALLY - LOGIC (SR0300.3.1.1.1)

- Trigger: Exception is selected

- Postcondition: Barcode string is entered manually

| Step | # | Description |
|------|---|-------------|
| Operator confirms exception | 10 | If entered barcode string does not match an equipment entity, phase displays the **Cannot find entity (SR0300.3.6.1)** error message (GID-2669528). |
| Operator signs exception | 20 | If equipment entity can be identified as an existing entity and exception is signed, phase continues with **Identify equipment entity (SR0300.2.3)** function (GID-2669520)(see also **Identify and bind equipment entity (SR0300.2.1)** function (GID-2669518). |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 3.4.2.3 GID-2671424 UNDO IDENTIFICATION (SR0300.3.1.2)

The **Undo identification** exception allows an operator to revoke the identification of an equipment entity or an equipment entity group.

In case an identified entity or entity group has been added to a pre-defined parent entity according to the **Parent entity of group (SR0300.8.6)** process parameter link, the exception also revokes this grouping.

The exception is disabled, if the required equipment entity or entity group is not in the **Bound** status.

Representation during exception handling:

- Instruction:
  Undo the identification of the entity.
  **Confirm** button.

- Exception text:
  <Exception text>
  (taken from **Undo identification (SR0300.8.4)** process parameter (GID-2671834))
  Released entity (group): <Equipment (parent) entity identifier> / <Equipment (parent) entity short description>

  - Example:
    Undo of identification during identification process
    Released entity (group): 23478H / Hose 45 cm

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 3.4.2.4 GID-2671425 Undo identification - Logic (SR0300.3.1.2.1)

Trigger: Exception is selected

Postcondition: Equipment entity or entity group is no longer bound

| Step | # | Description |
|---|---|---|
| Operator confirms exception | 10 | Phase shows exception description to be signed according to **Undo identification (SR0300.8.4)** process parameter (GID-2671834). |
| Operator signs exception | 20 | The following logic either applies to a single entity or to a main parent entity (not to child entities of a group): |
| | | ▪ If the identified equipment entity has been assigned to the pre-defined parent entity according to the **Parent entity of group (SR0300.8.6)** process parameter (GID-2671824): Phase separates the identified equipment entity from the pre-defined parent entity. |
| | | The following logic either applies to a single entity or to a main parent entity and to all of its child entities, respectively: |
| | | ▪ Phase resets the binding status of equipment entity to **Available** and updates the binding context in the **Context** tab of the equipment entity (not for workflows) and the logbook accordingly (Unbind) (if maintained). |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 3.4.2.5 GID-2671426 Skip identification (SR0300.3.1.3)

The **Skip identification** exception allows an operator to skip the identification of an equipment entity or an equipment entity group.

The exception is disabled, if the required equipment entity or entity group is in the **Identified** or **Bound** status.

Representation during exception handling:

▪ Instruction:
Skip the identification.
**Confirm** button.

▪ Exception text:
&lt;Exception text&gt;
(taken from **Skip identification (SR0300.8.11)** process parameter (GID-2671835))
No equipment entity identified.

■ Example:
Identification of further equipment entities to load autoclave has been skipped.
No equipment entity identified.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 3.4.2.6 GID-2671427 SKIP IDENTIFICATION - LOGIC (SR0300.3.1.3.1)

Trigger: Exception is selected

Postcondition: Phase can be completed without equipment entity identification

| Step | # | Description |
|---|---|---|
| Operator confirms exception | 10 | Phase shows exception description to be signed according to **Skip identification (SR0300.8.11)** process parameter (GID-2671835). |
| Operator signs exception | 20 | Phase returns to the Execution Window and can be completed without having identified an equipment entity.<br>Phase sets the **Result (SR0300.9.4)** output variable (GID-2669537)to SKIPPED. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 3.4.3  Post-completion Exceptions

There are no post-completion exceptions available.

## 3.5  Information Messages

There are no information messages available.

## 3.6  Questions

There are no questions available.

## 3.7  Decisions

There are no decisions available.

## 3.8  Error Messages (SR0300.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

### 3.8.1 GID-2669528 Cannot find entity (SR0300.3.6.1)

| UI text | Comment |
|---|---|
| Cannot identify the <scanned identifier> entity, since it is not available in the system. | Message pack: PhaseEqmEqIdentification<version><br>Message ID: EqNotExist_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.8.2 GID-2669529 Already identified (SR0300.3.6.2)

| UI text | Comment |
|---|---|
| Cannot identify the <scanned identifier> entity, since you have already identified a suitable entity. To identify another entity, revoke the identification of the <currently identified identifier> entity first. | Message pack: PhaseEqmEqIdentification<version><br>Message ID: EqReqAlreadyIdent_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 3.8.2.1 GID-2671428 NOT MEMBER OF REQUIRED CLASS (SR0300.3.6.3)

| UI text | Comment |
|---|---|
| The <scanned entity or main parent identifier> equipment entity is not suitable, since it does not belong to the required class (<class identifier>). | Message pack: eqm.Validation<br>Message ID: eqmClassNotMatch_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.8.2.2 GID-2671429 NOT AVAILABLE FOR USAGE (SR0300.3.6.4)

| UI text | Comment |
|---|---|
| Cannot identify the <identifier> equipment entity, since it has already been identified or bound at the <identifier> work center for <workflow, order> (unit procedure: <identifier>, operation: <identifier>, phase: <identifier>). | If the **Identify in current binding context (SR0300.8.7)** process parameter (GID-2671825)is set to **No**: Applies either to a single entity or to a main parent entity (not to child entities of a group).<br><br>Message pack: fsm_S88EquipmentBinding<br>Message ID: identifyNotAllowedOwnedByOther_ErrorMsg |
| Cannot identify the <parent identifier> equipment entity, since at least one of its child entities has already been identified or bound. | If the **Identify in current binding context (SR0300.8.7)** process parameter  (GID-2671825)is set to **No**: Applies if the check only fails for at least one child entity of a group.<br><br>Message pack: fsm_S88EquipmentBinding<br>Message ID: identifyDescendantNotAllowedOwnedByOther_ErrorMsg |
| Cannot identify the <identifier> equipment entity, since it is not yet bound to an allowed unit procedure context. | If the **Identify in current binding context (SR0300.8.7)** process parameter (GID-2671825)is set to **Yes**: Applies either to a single entity or to a main parent entity (not to child entities of a group).<br><br>Message pack: fsm_S88EquipmentBinding<br>Message ID: identifyNotAllowedIncompatibleBindingContext_ErrorMsg |

| UI text | Comment |
|---------|---------|
| Cannot identify the <parent identifier> equipment entity, since at least one of its child entities is not yet bound to an allowed unit procedure context. | If the **Identify in current binding context (SR0300.8.7)** process parameter (GID-2671825)is set to **Yes**: Applies if the check only fails for at least one child entity of a group. Message pack: fsm_S88EquipmentBinding Message ID: identifyDescendantNotAllowedIncompatibleBindingContext_ErrorMsg |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.8.2.3 GID-2671430 NOTHING IDENTIFIED (SR0300.3.6.5)

| UI text | Comment |
|---------|---------|
| You have to identify an entity before you can confirm the phase. | Message pack: PhaseEqmEqIdentification<version> Message ID: EqNotIdentified_ErrorMsg |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Medium |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.8.2.4 GID-2671431 EXPIRED TRIGGER EXECUTION FAILED (SR0300.3.6.9)

| UI text | Comment |
|---------|---------|
| ▪ The <equipment identifier> entity is not suitable, since the update of at least one expired status failed. ▪ The <equipment identifier> entity group is not suitable, since the update of at least one expired status failed. | ▪ Message pack: pec_ExceptionMessage Message ID: cannotIdentifyExpiryTriggerFailure_ErrorMsg ▪ Message pack: pec_ExceptionMessage Message ID: cannotIdentifyExpiryTriggerGroupFailure_ErrorMsg |

| UI text | Comment |
|---------|---------|
|  | The **Details** button provides access to more graph-specific information (for each entity of an entity group):<br><br><the reason that applies><br>Equipment: <equipment identifier> / <equipment short description><br>Equipment type: <list of equipment types> (if available)<br>Graph (ID): <graph display text> (<identifier>)<br>Purpose: <purpose><br>Current status (key): <display text> (<key>)<br>Failed trigger (key): <display text> (<key>)<br><br>The potential reasons for a failed status transition are:<br><br>▪ Cannot find a transition for the current status.<br><br>▪ Cannot find a fulfillable transition condition for the current status.<br><br>▪ There is more than one fulfillable transition condition available for the current status: <TR-ID; TR-ID; ...>.<br><br>▪ Cannot evaluate the transition condition (<TR-ID>).<br><br>▪ Cannot evaluate the transition action (<TR-Action ID>) from the current status to the new status (<display text (key)>). |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.8.2.5 GID-2671432 ENTITY IS PART OF A GROUP (SR0300.3.6.10)

| UI text | Comment |
|---------|---------|
| Cannot identify the <identifier> equipment entity, since it is a member or the parent of a group (<parent identifier>). | Message pack: PhaseEqmEqIdentification<version><br>Message ID: EqPartOfGroup_ErrorMsg |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.8.2.6 GID-2671433 ENTITY IS NOT PART OF A GROUP (SR0300.3.6.11)

| UI text | Comment |
|---|---|
| Cannot identify the <identifier> equipment entity, since it is not a member of a group. | Message pack: PhaseEqmEqIdentification<version><br>Message ID: EqNotPartOfGroup_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.8.2.7 GID-2671434 GROUP CYCLE ERROR (SR0300.3.6.12)

| UI text | Comment |
|---|---|
| Cannot add the <identifier> equipment entity to the group, since it already belongs to the group, either as member of a sub-group or as member of the main group. | Message pack: eqm.Validation<br>Message ID: eqmGroupCycle_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.8.2.8 GID-2671435 NOT A CHILD ENTITY OF BOUND GROUP (SR0300.3.6.13)

| UI text | Comment |
|---|---|
| Cannot identify the <identifier> equipment entity, since it is not a child entity of an already bound group or there is a configuration issue in the phase. | Message pack: PhaseEqmEqIdentification<version><br>Message ID: EqIsNotBoundChildOfGroup_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.8.2.9 GID-2671436 PARENT ENTITY NOT BOUND (SR0300.3.6.14)

| UI text | Comment |
|---|---|
| Cannot identify the child entity, since the parent of the group is not available. | Message pack: PhaseEqmEqIdentification<version><br>Message ID: EqParentDoesNotExistButIsRequired_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 3.9 Output Variables (SR0300.9+)

The following output variables are available to reference the phase's output.

### 3.9.1 Instance count (Framework capability)

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

### 3.9.2 Start time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

### 3.9.3 Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

### 3.9.4 Identifier (Framework capability)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

### 3.9.5 GID-2669534 Equipment object (SR0300.9.1)

- Data type: IMESS88Equipment

- Usage: The output variable provides the complete object of the identified equipment entity. This is the output to use in subsequent phases for accessing data of the equipment object, such as changing its status or writing a property.
  In case an entity group has been identified, the main parent entity of the entity group is provided.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.9.6  GID-2669535 Equipment ID (SR0300.9.2)

- Data type: String

- Usage: The output variable provides the identifier of the identified equipment entity for displaying it as text.
  In case an entity group has been identified, the main parent entity of the entity group is provided.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.9.7  GID-2669536 Equipment short description (SR0300.9.3)

- Data type: String

- Usage: The output variable provides the short description of the identified equipment entity for displaying it as text.
  In case an entity group has been identified, the main parent entity of the entity group is provided.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 3.9.8  GID-2669537 Result (SR0300.9.4)

- Data type: String

- Values: SKIPPED, IDENTIFIED

- Usage: The output variable states if an equipment entity has been identified:

- The value is SKIPPED if the phase has been completed without identifying an equipment entity.

- The value is IDENTIFIED if an equipment entity has been identified and thus bound.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

# 4 Change Equipment Status Phase (SR0310+)

The **Change equipment status** phase allows an operator to set an FSM-related status of a previously identified equipment entity.

The phase neither supports equipment graphs that are maintained in Data Manager - Equipment nor equipment entity groups.

An example use case is:

- Need to set the equipment entity's status
  Depending on the current process step, the status must be changed from **Clean** to **In use**.
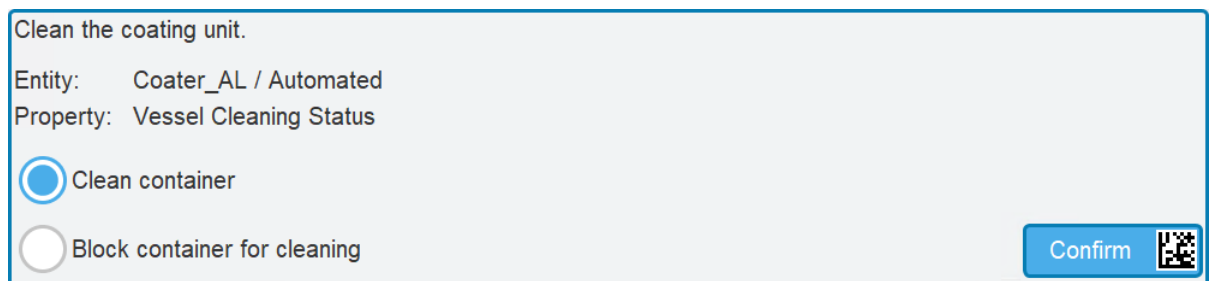
The affected equipment entity, its FSM property, the performed action, and the old and new statuses are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2671444).

Anomalies that occur during processing are covered by the phase exception handling (GID-2668282)(e.g. status change failed).

After completion the phase displays the affected equipment entity with the following data in the Execution Window:

- Entity identifier and short description

- Property identifier

- Performed action

- Old status

- New status

The Navigator displays the identifier of the affected equipment entity.



*Figure 13: Change equipment status during execution*

## 4.1 Layout

The phase provides individual layouts for its representation during execution (GID-2669538), in the Navigator (GID-2669539), and in the sub-report (GID-2669540).

### 4.1.1 Representation during Execution (SR0310.1+)

The representation during execution depends on the phase mode.

#### 4.1.1.1 GID-2671437 PREVIEW MODE (SR0310.1.1)

1. <Instruction text>
   (taken from **Instruction (SR0310.8.1)** process parameter (GID-2671449))

2. Entity:

3. Property: <property identifier>
   (taken from **Allowed change actions (SR0310.8.3)** process parameter (GID-2671451))

4. List of allowed actions
   (taken from **Allowed change actions (SR0310.8.3)** process parameter (GID-2671451))

5. **Confirm** button (disabled).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Medium |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 4.1.1.2 GID-2671438 ACTIVE MODE (SR0310.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0310.8.1)** process parameter (GID-2671449))

3. Entity: <equipment entity identifier> / <equipment entity short description>
   (taken from **Identified equipment entity (SR0310.8.2)** process parameter (GID-2671450))

4. Property: <property identifier>
   (taken from **Allowed change actions (SR0310.8.3)** process parameter (GID-2671451))

5. List of available actions
   (taken from **Allowed change actions (SR0310.8.3)** process parameter (GID-2671451))
   Based on the actual status of the identified equipment entity, the phase displays only the available actions from the list of allowed actions.

6. **Confirm** button.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 4.1.1.3 GID-2671439 COMPLETED MODE (SR0310.1.3)

1.  Instruction table panel and/or instruction link panel
    (only if an instruction table and/or instruction link is defined for the phase)

2.  <Instruction text>
    (taken from **Instruction (SR0310.8.1)** process parameter (GID-2671449))

3.  Entity: <equipment entity identifier> / <equipment entity short description>
    (taken from **Identified equipment entity (SR0310.8.2)** process parameter (GID-2671450))

4.  Property: <property identifier>
    (taken from **Allowed change actions (SR0310.8.3)** process parameter (GID-2671451))

5.  Performed action: <action>

6.  New status: <status>

7.  **Confirm** button (completed).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 4.1.2 Representation in Navigator (SR0310.4+)

The Navigator provides the following details:

### 4.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

▪ <Phase name>

   ▪ Example:
     Set status of blender

### 4.1.2.2 GID-2671441 INFORMATION COLUMN (SR0310.4.1)

▪ <Identifier of affected equipment entity>

   ▪ Example: BlenderA12

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Low |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 4.1.2.3 ACTION COLUMN

▪ There are no actions available.

## 4.1.3 Representation in Sub-report (SR0310.5+)

The sub-report contains the following information:

#### 4.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- \<Start time>

- \<Completion time>

- \<Unit procedure> / \<operation> / \<phase>

- \<Work center> / \<station> / \<device> - \<phase completion user>

#### 4.1.3.2 GID-2671444 SUB-REPORT ELEMENTS (SR0310.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Instruction text

- Entity (identifier and short description)

- FSM property (identifier)

- Performed action

- Old status

- New status

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 4.2 Business Logic (SR0310.2+)

The phase implements the following business logic.

### 4.2.1 GID-2669541 Determine available actions (SR0310.2.1)

- Function: Determine available actions of pre-defined FSM for affected equipment entity

- Trigger: Phase becomes active

- Postcondition: Available actions are displayed

| Step | # | Description |
|---|---|---|
| Phase activation | 10 | Phase displays its user interface according to the **Active mode (SR0310.1.2)** layout (GID-2671438). |

| Step | # | Description |
|------|---|-------------|
| Phase checks if the referenced equipment entity is available at runtime | 20 | If the check fails, phase creates the **Equipment data mismatch (SR0310.3.2.1)** system-triggered exception (GID-2671455). |
| Phase checks if the property type fits the equipment entity | 30 | ▪ If the check fails, phase creates the **Equipment data mismatch (SR0310.3.2.1)** system-triggered exception (GID-2671455).<br>▪ If the check passes successfully, phase continues with the next check. |
| Phase checks for available actions | 40 | ▪ Based on the actual status of the identified equipment entity and the settings of the **Allowed change actions (SR0310.8.3)** process parameter (GID-2671451), phase displays the list of all available actions.<br>▪ Phase continues with the **Perform status change (SR0310.2.2)** function (GID-2669542). |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 4.2.2 GID-2669542 Perform status change (SR0310.2.2)

- ▪ Function: Perform a status change on the equipment entity

- ▪ Trigger: Operator confirms phase

- ▪ Postcondition: Status is set

| Step | # | Description |
|------|---|-------------|
| Operator confirms phase without having selected an action | 10 | Phase displays the **No action selected (SR0310.3.6.1)** error message (GID-2669552). |
| Operator selects action and confirms phase | 20 | ▪ If previously executed checks still fail (e.g. system-triggered exception has been canceled), phase creates the **Equipment data mismatch (SR0310.3.2.1)** system-triggered exception (GID-2671455). |

| Step | # | Description |
|------|---|-------------|
| | | ▪ If the action cannot be performed, phase displays the **Change action failed (SR0310.3.6.2)** error message [(GID-2669553)](). |
| | | ▪ If the action was successful, phase sets the new status of the equipment entity. |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 4.3 Process Parameters (SR0310.8+)

The following process parameters define the behavior of the phase.

### 4.3.1 Instruction Table-specific Parameters

#### 4.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|-----------|------|---------|
| Table layout | Choice list | Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**. |
| First column narrow | Boolean | Defines if the first column of the table shall be narrow. |
| Show all borders | Boolean | Defines if the borders of the table shall be visible. |

### 4.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Column 1 | HTML text | Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags). |
| Column 2 | HTML text | |
| Column 3 | HTML text | |
| Column 4 | HTML text | |
| Column 5 | HTML text | |

## 4.3.2  Instruction Link-specific Parameters

### 4.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Instruction text | HTML text | Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671448). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags). |

### 4.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Link text | Text | Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters. |

| Attribute | Type | Comment |
|-----------|------|---------|
| Link URL | Text | URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system.<br><br>Maximum length is 256 characters. |

### 4.3.3  Basic Parameters

#### 4.3.3.1 GID-2671449 INSTRUCTION (SR0310.8.1)

| Attribute | Type | Comment |
|-----------|------|---------|
| Column 1 | HTML text | Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags). |
| Column 2 | HTML text | Not used. |
| Column 3 | HTML text | |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 4.3.3.2 GID-2671450 IDENTIFIED EQUIPMENT ENTITY (SR0310.8.2)

| Attribute | Type | Comment |
|-----------|------|---------|
| Equipment object | Reference | Reference to the output of a preceding phase that provides an identified equipment entity. |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 4.3.4 Property Type Parameters

#### 4.3.4.1 GID-2671451 ALLOWED CHANGE ACTIONS (SR0310.8.3)

| Attribute | Type | Comment |
|---|---|---|
| Property and allowed change actions | Text (structured) | The property that needs to match the respective status property of the identified equipment entity on the shop floor and the allowed actions from the list of all supported actions of the selected property. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 4.3.4.2 GID-2671452 CHANGE ACTION SELECTION EDITOR (SR0310.8.3.1)

The system provides a Change Action Selection editor for selecting change actions based on their property type.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 4.3.5 Configuration of System-triggered Exceptions

#### 4.3.5.1 GID-2671453 EQUIPMENT DATA MISMATCH (SR0310.8.4)

| Attribute | Type | Comment |
|---|---|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.<br>Available settings: **None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).**<br>Default setting: **High**, defined by the **DefaultRiskClassForPhaseProcessParameter** configuration key. |
| Exception text | Text | Defines the exception description used during exception handling and within the batch record.<br>Maximum length is 256 characters. |

> See also **Equipment data mismatch (SR0310.3.2.1)** system-triggered exception (GID-2671455).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 4.3.6  Configuration of User-triggered Exceptions

#### 4.3.6.1 GID-2671454 FORCE STATUS (SR0310.8.5)

| Attribute | Type | Comment |
|---|---|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.<br>Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**.<br><br>Default setting: **High**, defined by the **DefaultRiskClassForPhaseProcessParameter** configuration key. |
| Exception text | Text | Defines the exception description used during exception handling and within the batch record.<br>Maximum length is 256 characters. |

> See also **Force status (SR0310.3.1.1)** user-triggered exception (GID-2671457).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 4.4  Exceptions (SR0310.3+)

The phase supports user-defined, user-triggered (GID-2669550), system-triggered (GID-2669549), and post-completion exceptions (GID-2668286)and their configuration by means of process parameters (GID-2668281).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

### 4.4.1  GID-2669549 System-triggered Exceptions (SR0310.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | No |
| MES-Business: Business Impact | None |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 4.4.1.1 GID-2671455 EQUIPMENT DATA MISMATCH (SR0310.3.2.1)

The exception text is extended by messages specific to the current situation.

Representation of the exception:

- \<Exception text>
  (taken from **Equipment data mismatch (SR0310.8.4)** process parameter (GID-2671453))

  - If the expected equipment is not available:
    Cannot find the expected entity.

  - If the property type check fails:
    The \<identifier> entity does not have a \<property identifier> property or the property has no FlexibleStateModel.

  - Example:
    Equipment data configuration error.
    The BlenderA12 entity does not have a CleaningBlender property.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

#### 4.4.1.2 GID-2671456 EQUIPMENT DATA MISMATCH - LOGIC (SR0310.3.2.1.1)

- Trigger: Equipment entity or property type do not match

- Postcondition: Exception is recorded

| Step | # | Description |
|---|---|---|
| Operator triggers exception | 10 | Phase records the exception. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 4.4.2 GID-2669550 User-triggered Exceptions (SR0310.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | No |
| MES-Business: Business Impact | None |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 4.4.2.1 GID-2671457 FORCE STATUS (SR0310.3.1.1)

The **Force status** exception allows an operator to force a status change or to keep the current status.

Representation during exception handling:

▪ Instruction:
   Force status:
   Display of possible target statuses and the **<current status> (keep current status)** option.
   **Confirm** button.

   ▪ Exception text:
      <Exception text>
      (taken from **Force status (SR0310.8.5)** process parameter (GID-2671454))
      <Identifier> property of <identifier> entity was forced to <target status> status.

   ▪ Example:
      Status change forced
      CleaningBlender property of BlenderA12 entity was forced to Clean status.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

#### 4.4.2.2 GID-2671458 FORCE STATUS - LOGIC (SR0310.3.1.1.1)

- Trigger: Exception is selected

- Postcondition: Status of equipment entity is set

| Step | # | Description |
|------|---|-------------|
| Operator selects status | 10 | Phase displays all available target statuses of the equipment entity, based on the list of allowed actions (see **Allowed change actions (SR0310.8.3)** process parameter (GID-2671451). The selected status is marked. |
| Operator confirms exception | 20 | Phase shows exception description to be signed according to **Force status (SR0310.8.5)** process parameter (GID-2671454). |
| Operator signs exception | 30 | Phase sets status of equipment entity to the selected one and records the exception. |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 4.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

## 4.5 Information Messages

There are no information messages available.

## 4.6 Questions

There are no questions available.

## 4.7 Decisions

There are no decisions available.

## 4.8 Error Messages (SR0310.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

### *4.8.1 GID-2669552 No action selected (SR0310.3.6.1)*

| UI text | Comment |
|---|---|
| You have to select an action before you can confirm. | Message pack: PhaseEqmEqChangeStatus<version><br>Message ID: HintUserSelectionRequired_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Medium |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### *4.8.2 GID-2669553 Change action failed (SR0310.3.6.2)*

| UI text | Comment |
|---|---|
| <action> action failed for the <identifier> property of the <identifier> equipment.<br><details of failure> | Message pack: PhaseEqmEqChangeStatus<version><br>Message ID: TransitionFailed_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 4.9 Output Variables (SR0310.9+)

The following output variables are available to reference the phase's output.

### *4.9.1 Instance count (Framework capability)*

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

### *4.9.2 Start time (Framework capability)*

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

### 4.9.3  Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

### 4.9.4  Identifier (Framework capability)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

### 4.9.5  GID-2669558 Status change result (SR0310.9.1)

- Data type: String

- Values: PLANNED, FORCED, SKIPPED

- Usage: The output variable states the conditions under which the status change has been performed.

  - The value is PLANNED if the status change has been performed as defined in the phase.

  - The value is FORCED if the status change has been forced by the operator.

  - The value is SKIPPED if no status change has been performed at all (**Keep current status** option).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 4.9.6  GID-2669559 New status (SR0310.9.2)

- Data type: String

- Usage: The output variable provides the new status of the equipment entity.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

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# 5 Trigger Graph Transition Phase (SR0311+)

The **Trigger graph transition** phase allows an operator to change an equipment graph-related status of a previously identified equipment entity or equipment entity group (parent entity and its child entities) by executing a graph trigger.

An example use case is:

- Need to trigger a graph transition on the equipment entity
Depending on entity properties like counter, dates, and the current status, a trigger causes a status transition from **In use** to **Reusable** or **Uncleaned**.
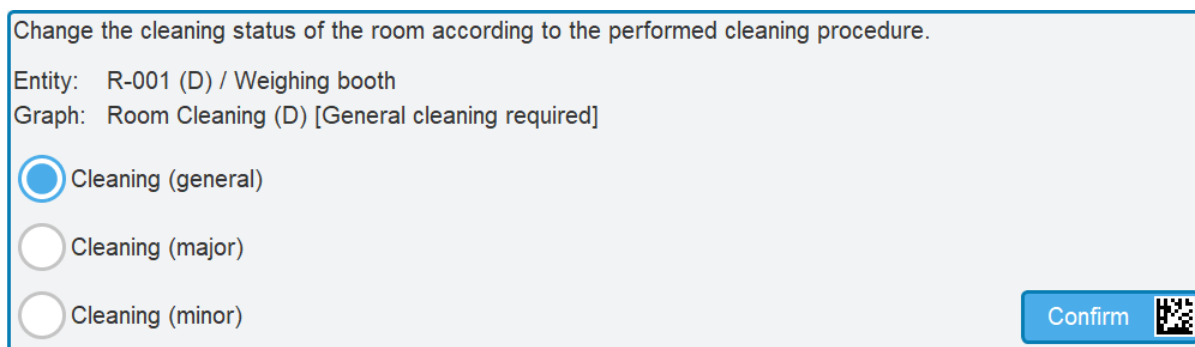
The affected equipment entities, their equipment graphs, the performed trigger, and the old and new statuses are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669562).

Anomalies that occur during processing are covered by the phase exception handling (GID-2669570)(e.g. no transition exists for the current status).

After completion the phase displays the identified equipment entity with the following data in the Execution Window:

- Entity identifier and short description
(of a single entity or a main parent entity of a group)

- Equipment graph

- Performed trigger

- Old status

- New status

- List of child entities (if applicable)

The Navigator displays the identifier of the identified equipment entity and the number of child entities that hold an equipment graph of the configured purpose (if applicable).



*Figure 14: Trigger graph transition during execution*

Set the cleaning status for the sterilized components.

Entity: SterilizationTray / For assembly parts of Automated Tablet Press
Graph: Unit Cleaning Graph [To be cleaned]

List of child entities of SterilizationTray / For assembly parts of Automated Tablet Press

| Identifier | Short description | Statuses |
|---|---|---|
| TabletDischargeChute-AS | Discharge Chute for Automated Tablet Press | - Unit Cleaning Graph / To be cleaned |
| TabletPressFeeder-AS | Feeder for Automated Tablet Press | - Unit Cleaning Graph / To be cleaned |
| TabletPressFeederSeal-AS | Feeder Seal for Automated Tablet Press | - Unit Cleaning Graph / To be cleaned |

Cleaned                                                                      Confirm

*Figure 15: Trigger graph transition during execution*

## 5.1 Layout

The phase provides individual layouts for its representation during execution (GID-2671459), in the Navigator (GID-2792696), and in the sub-report (GID-2671466).

### 5.1.1 Representation during Execution (SR0311.1+)

The representation during execution depends on the phase mode.

#### 5.1.1.1 GID-2671459 PREVIEW MODE (SR0311.1.1)

1. <Instruction text>
   (taken from **Instruction (SR0311.8.1)** process parameter (GID-2671475))

2. Entity:

3. Graph:

4. List of child entities of the group

   ▪ Only if the **Show children (SR0311.8.7)** process parameter (GID-2671478)is set to **Yes**.

5. List of allowed triggers
   (taken from **Allowed triggers (SR0311.8.4)** process parameter (GID-2671479))
   The phase displays the complete list of allowed triggers with their key.

6. **Confirm** button (disabled).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Medium |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 5.1.1.2 GID-2671460 ACTIVE MODE (SR0311.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0311.8.1)** process parameter (GID-2671475))

3. Entity: <equipment entity identifier> / <equipment entity short description>
   (taken from **Identified equipment entity (SR0311.8.2)** process parameter (GID-2671476))

4. Graph: <equipment graph display text> [<equipment graph current status>]
   (equipment graph is determined by the purpose taken from **Allowed triggers (SR0311.8.4)**
   process parameter (GID-2671479), current status has to be stored at activation for later use as old
   status)

   ▪ In case of an entity group, this is the graph of the main parent entity. If it does not exist,
     phase displays "N/A".

5. List of child entities

   ▪ Only in case of an entity group and if the **Show children (SR0311.8.7)** process
     parameter (GID-2671478)is set to **Yes**.

   ▪ Only if the list is not empty: includes only entities that hold an equipment graph of the
     configured purpose.

   ▪ Details of child entity.

   | <Child entity identifier> | <Child entity short description> | <equipment graph display text> [<equipment graph old status>] |
   |---|---|---|

6. List of allowed triggers
   (taken from **Allowed triggers (SR0311.8.4)** process parameter (GID-2671479))
   The phase displays the complete list of allowed triggers with their display text.

   ▪ If the display text is not unique, phase displays the key of the trigger.

   ▪ If the trigger is not available at any entity, phase displays "<trigger key> (N/A)".

   ▪ If the trigger is not available at all entities to which the graph is assigned, phase displays
     "<trigger key/display text> (incomplete)".

7. **Confirm** button.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 5.1.1.3 GID-2671461 COMPLETED MODE (SR0311.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0311.8.1)** process parameter (GID-2671475))

3. Entity: <equipment entity identifier> / <equipment entity short description>
   (taken from **Identified equipment entity (SR0311.8.2)** process parameter (GID-2671476))

4. Graph: <equipment graph display text> [<equipment graph current status>]
   (equipment graph is determined by the purpose taken from **Allowed triggers (SR0311.8.4)** process parameter (GID-2671479))

   ▪ In case of an entity group, this is the graph of the main parent entity. If it does not exist, phase displays "N/A".

5. Performed trigger: <trigger display text>

6. Old status: <equipment graph old status>
   (old status is taken from value stored at **Active mode (SR0311.1.2)** layout (GID-2671460))

   ▪ In case of an entity group, this is the old status of the main parent entity. If it does not exist, phase displays "N/A".

7. New status: <equipment graph current status>

   ▪ In case of an entity group, this is the new status of the main parent entity. If it does not exist, phase displays "N/A".

8. List of child entities

   ▪ Only in case of an entity group and if the **Show children (SR0311.8.7)** process parameter (GID-2671478)is set to **Yes**.

   ▪ Only if the list is not empty: includes only entities that hold an equipment graph of the configured purpose.

   ▪ Details of child entity.

| <Child entity identifier> | <Child entity short description> | <equipment graph display text> [<equipment graph new status>] |
|---|---|---|

9. **Confirm** button (completed).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### *5.1.2 Representation in Navigator (SR0311.4+)*

The Navigator provides the following details:

#### 5.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>

    - Example:
      Set container to cleaned

#### 5.1.2.2 GID-2671463 INFORMATION COLUMN (SR0311.4.1)

- <Identifier of affected equipment entity>

- Example: Gran0033

- Only in case of an entity group

    - <Identifier of affected equipment entity>
      <Number of child entities that hold an equipment graph of the configured purpose> child entities

        - Example:
          Gran0033
          5 child entities

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Low |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 5.1.2.3 ACTION COLUMN

- There are no actions available.

### *5.1.3 Representation in Sub-report (SR0311.5+)*

The sub-report contains the following information:

#### 5.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>

- <Completion time>

- <Unit procedure> / <operation> / <phase>

- <Work center> / <station> / <device> - <phase completion user>

#### 5.1.3.2 GID-2671466 SUB-REPORT ELEMENTS (SR0311.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Instruction text

- Entity: <identifier> / <short description>

- Equipment graph (ID): <display text> (key)

  - In case of an entity group, this is the graph of the main parent entity. If it does not exist, phase displays "N/A".

- Performed trigger (key): <display text> (key)

- Old status (key): <display text> (key)

  - In case of an entity group, this is the old status of the main parent entity. If it does not exist, phase displays "N/A".

- New status (key): <display text> (key)

  - In case of an entity group, this is the new status of the main parent entity. If it does not exist, phase displays "N/A".

- Child equipment entities (identifier, short description, graph display text [new status])

  - Only in case of an entity group.

  - Includes only entities that hold an equipment graph of the configured purpose.

- <Phase completion signature>
  (only if a phase completion signature is assigned to the phase)

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 5.2 Business Logic (SR0311.2+)

The phase implements the following business logic.

### 5.2.1 Phase Mode

Business logic related to phase modes.

#### 5.2.1.1 GID-2671467 MANUAL COMPLETION MODE (SR0311.2.1)

- Function: **Manual completion** mode of phase

- Type: Phase mode

- Trigger: Phase becomes active

- Postcondition: Phase is active

| Step | # | Description |
|---|---|---|
| Phase activation | 10 | Phase displays its user interface according to the **Active mode (SR0311.1.2)** layout (GID-2671460) |
| Operator interaction | 20 | Operator selects a trigger of the equipment graph (see **Determine available triggers (SR0311.2.3)** function (GID-2671469)). |
| Phase completion | 30 | See **Trigger graph transition (SR0311.2.4)** function (GID-2671470). |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 5.2.1.2 GID-2671468 AUTOMATIC COMPLETION MODE (SR0311.2.2)

- Function: **Automatic completion** mode of phase

- Type: Phase mode

- Trigger: Phase becomes active

- Postcondition: Phase is completed

| Step | # | Description |
|---|---|---|
| Phase activation | 10 | Phase displays its user interface according to the **Active mode (SR0311.1.2)** layout (GID-2671460). |
| Phase determines available trigger | 20 | See **Determine available triggers (SR0311.2.3)** function (GID-2671469)<br><br>- If more than one trigger is available, phase must be completed manually. See **Manual completion (SR0311.2.1)** mode (GID-2671467).<br>- If a phase completion signature is assigned, the phase must be completed manually. See **Manual completion (SR0311.2.1)** mode (GID-2671467). |
| Phase performs trigger | | See **Trigger graph transition (SR0311.2.4)** function (GID-2671470).<br><br>- If no error has occurred, phase is completed automatically.<br>- If an error has occurred, phase must be completed manually. See **Manual completion (SR0311.2.1)** mode (GID-2671467). |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 5.2.2 *Main Path*

Business logic related to the main path:

#### 5.2.2.1 GID-2671469 DETERMINE AVAILABLE TRIGGERS (SR0311.2.3)

- Function: Determine available triggers of the pre-defined purpose for affected equipment entities

- Type: Main path

- Trigger: Phase becomes active

- Postcondition: Available triggers are displayed

| Step | # | Description |
|---|---|---|
| Phase activation | 10 | Phase displays its user interface according to the **Active mode (SR0311.1.2)** layout (GID-2671460)and performs checks based on the settings of the **Identified equipment entity (SR0311.8.3)** process parameter (GID-2671477)and the **Allowed triggers (SR0311.8.4)** process parameter (GID-2671479).<br><br>**TIP**<br>If a check fails, phase displays an appropriate error message that has to be confirmed with OK. The system-triggered exception related to the failed check is created upon phase completion. |
| Phase checks if the referenced equipment entity is available at runtime | 20 | ▪ If the **Identified equipment entity (SR0311.8.3)** process parameter (GID-2671477)is null, phase displays the **Entity not available (SR0311.3.6.2)** error message (GID-2669574).<br>▪ If the check passes successfully, phase continues with the next check. |
| Phase checks entity of group | 25 | ▪ In case of an entity group and if the entity is not the main parent entity of the group, phase displays the **Entity not main parent (SR0311.3.6.6)** error message (GID-2669575).<br>▪ If the check passes successfully, phase continues with the next check. |
| Phase checks if the purpose fits the equipment entity | 30 | The following check either applies to a single entity or to a main parent entity and to all of its child entities, respectively:<br>▪ If none of the graphs assigned to the equipment entities matches the pre-defined purpose according to the **Allowed triggers (SR0311.8.4)** process parameter (GID-2671479), phase displays the **Graph with purpose not assigned to entity (SR0311.3.6.3)** error message (GID-2669576).<br>▪ If the check passes successfully, phase continues with the next check. |

| Step | # | Description |
|---|---|---|
| Phase checks for available triggers | 40 | The following logic and check either applies to a single entity or to a main parent entity and to all of its child entities, respectively:<br><br>▪ Based on settings of the **Allowed triggers (SR0311.8.4)** process parameter (GID-2671479), phase displays the list of all configured triggers.<br><br>▪ If triggers are not available at any of the determined graphs, phase displays the key of the missing trigger and appends "(N/A)" to the key.<br><br>▪ If triggers are not available at all of the determined graphs, phase displays the key/display text of the trigger and appends "(incomplete)".<br><br>▪ If triggers are available, but their display text is not unique (within a graph or between graphs), phase displays the key of the trigger instead of any display text.<br><br>▪ If only one trigger is available, phase automatically selects the trigger.<br><br>▪ If no trigger is available, phase displays the **No trigger is available (SR0311.3.6.4)** error message (GID-2669577). |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 5.2.2.2 GID-2671470 TRIGGER GRAPH TRANSITION (SR0311.2.4)

▪ Function: Trigger graph transition on the equipment entities

▪ Type: Main path

▪ Trigger: Operator confirms phase

▪ Postcondition: Graph status transition and graph transition actions are done and/or phase is completed

| Step | # | Description |
|---|---|---|
| Operator confirms phase without having selected a trigger | 10 | Phase displays the **No trigger selected (SR0311.3.6.1)** error message (GID-2669573). |

| Step | # | Description |
|------|---|-------------|
| Operator selects a trigger and confirms the phase | 20 | The following logic either applies to a single entity or to a main parent entity and to all of its child entities, respectively:<br><br>▪ If a phase completion signature is assigned, the signature is requested.<br><br>▪ If previously executed checks of the **Determine available triggers (SR0311.2.3)** function (GID-2671469)still fail, phase creates the **Equipment data mismatch (SR0311.3.2.1)** system-triggered exception (GID-2671483).<br><br>▪ Phase triggers the status transitions at all entities that hold an equipment graph of the configured purpose.<br><br>▪ If a status transition at any entity that holds an equipment graph of the configured purpose cannot be performed, phase creates the **Status transition failed (SR0311.3.2.2)** system-triggered exception (GID-2671485).<br><br>▪ If the status transitions were successful for all entities that hold an equipment graph of the configured purpose or the **Status transition failed (SR0311.3.2.2)** system-triggered exception (GID-2671485)was confirmed, phase reads the new status of each equipment entity.<br>**TIP**<br>A successful status transition depends on the transition configuration within the graph master data, including condition and action definitions. Properties of the equipment entity can be set along with the status transition, as defined at the transition actions. |
| A system-triggered exception has been canceled | 30 | The following logic either applies to a single entity or to a main parent entity and to all of its child entities, respectively:<br><br>▪ Phase cannot be completed without confirmation of created system-triggered exceptions.<br><br>▪ If the **Status transition failed (SR0311.3.2.2)** system-triggered exception (GID-2671485)is canceled:<br>Phase is still **active**, **no status transition** has been performed for any entity that holds an equipment graph of the configured purpose, and the operator can continue with a **different trigger** (if available). |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 5.3  Process Parameters (SR0311.8+)

The following process parameters define the behavior of the phase.

### 5.3.1  Instruction Table-specific Parameters

#### 5.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Table layout | Choice list | Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**.<br>Default setting: **1 column**. |
| First column narrow | Boolean | Defines if the first column of the table shall be narrow. |
| Show all borders | Boolean | Defines if the borders of the table shall be visible. |

#### 5.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Column 1 | HTML text | Instruction text to be displayed in a column.<br>**Restriction**: Maximum length is 2000 characters (including HTML tags). |
| Column 2 | HTML text | |
| Column 3 | HTML text | |
| Column 4 | HTML text | |
| Column 5 | HTML text | |

### *5.3.2 Instruction Link-specific Parameters*

#### 5.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Instruction text | HTML text | Instruction text to be displayed.<br>For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671474).<br>Example: Refer to {SOP1270} for guidance.<br><br>Maximum length is 2000 characters (including HTML tags). |

#### 5.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Link text | Text | Text to be used as link.<br>For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute.<br>Including the brackets in the link text is optional.<br><br>Maximum length is 80 characters. |
| Link URL | Text | URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system.<br><br>Maximum length is 256 characters. |

### 5.3.3  Basic Parameters

#### 5.3.3.1 GID-2671475 INSTRUCTION (SR0311.8.1)

| Attribute | Type | Comment |
|---|---|---|
| Text | HTML text | Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags). |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 5.3.3.2 GID-2671476 MODE (SR0311.8.2)

| Attribute | Type | Comment |
|---|---|---|
| Mode | Choice list | Defines the processing mode. **Manual completion (default)**: Operator confirms phase manually. **Automatic completion**: Phase is completed automatically if only one trigger is available. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 5.3.3.3 GID-2671477 IDENTIFIED EQUIPMENT ENTITY (SR0311.8.3)

| Attribute | Type | Comment |
|---|---|---|
| Equipment object | Reference | Reference to the output of a preceding phase that provides an identified equipment entity. In case of an entity group, the main parent entity of the group must be referenced. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 5.3.3.4 GID-2671478 SHOW CHILDREN (SR0311.8.7)

| Attribute | Type | Comment |
|-----------|------|---------|
| Enabled | Boolean | In case of an entity group: controls if the list of child entities is displayed during execution. If so, only entities that hold an equipment graph of the configured purpose are displayed. Default setting: **Yes** |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 5.3.4 Equipment Graph Parameters

### 5.3.4.1 GID-2671479 ALLOWED TRIGGERS (SR0311.8.4)

| Attribute | Type | Comment |
|-----------|------|---------|
| Purpose and allowed triggers | Text (structured) | Defines the equipment graph (based on its purpose) and the allowed triggers. The equipment graph needs to match an equipment graph of the identified equipment entity or entity group on the shop floor. |
| | | All equipment graphs of the identified entity or entity group with this purpose are affected during execution by the selected transition trigger. |
| | | **Restriction**: Maximum length is 4000 characters |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 5.3.4.2 TRIGGER SELECTION EDITOR (FRAMEWORK CAPABILITY)

The system provides a Trigger Selection editor for selecting triggers based on their equipment graph. The graph purpose determines which triggers of which equipment graphs are available. System triggers and triggers of graphs in the **Archived** status are not available.

### 5.3.5  Configuration of System-triggered Exceptions

#### 5.3.5.1 GID-2671481 EQUIPMENT DATA MISMATCH (SR0311.8.5)

| Attribute | Type | Comment |
|---|---|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.<br>Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**.<br><br>Default setting: **High**, defined by the **DefaultRiskClassForPhaseProcessParameter** configuration key. |
| Exception text | Text | Defines the exception description used during exception handling and within the batch record.<br>Maximum length is 256 characters. |

See also **Equipment data mismatch (SR0311.3.2.1)** system-triggered exception (GID-2671483).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 5.3.5.2 GID-2671482 STATUS TRANSITION FAILED (SR0311.8.6)

| Attribute | Type | Comment |
|---|---|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.<br>Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**.<br><br>Default setting: **High**, defined by the **DefaultRiskClassForPhaseProcessParameter** configuration key. |
| Exception text | Text | Defines the exception description used during exception handling and within the batch record.<br>Maximum length is 256 characters. |

See also **Status transition failed (SR0311.3.2.2)** system-triggered exception (GID-2671485).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 5.4 Exceptions (SR0311.3+)

(GID-2669572)The phase supports user-defined, user-triggered (GID-2669571), system-triggered (GID-2669570), and post-completion exceptions link and their configuration by means of process parameters (GID-2668290).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

### 5.4.1 System-triggered Exceptions (SR0311.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

#### 5.4.1.1 GID-2671483 Equipment data mismatch (SR0311.3.2.1)

The exception text is extended by messages specific to the current situation.

Representation of the exception:

Exception dialog

- \<Exception text>
  (taken from **Equipment data mismatch (SR0311.8.5)** process parameter (GID-2671481))

  - If the expected equipment is not available:
    Cannot find the expected entity.

  - In case of a single equipment entity:
    If an equipment graph of the purpose is not available at any entity:
    The \<identifier> entity does not hold an equipment graph of the \<purpose> purpose.

  - In case of an equipment group:
    If an equipment graph of the purpose is not available at all entities:
    None of the entities of the \<identifier> entity group holds an equipment graph of the \<purpose> purpose.

  - If no trigger is configured:
    No purpose or trigger available.

  - Example:
    Equipment data configuration error.
    The IBC0033 entity does not hold an equipment graph of the Container Cleaning (RS) purpose.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 5.4.1.2 GID-2671484 Equipment data mismatch - Logic (SR0311.3.2.1.1)

- Trigger: Equipment entity or equipment graph do not match or no trigger was configured.

- Postcondition: Exception is recorded and phase is completed

| Step | # | Description |
|---|---|---|
| Operator accepts exceptional situation | 1-10 | Phase shows exception description to be signed. |
| Operator signs exception | 1-20 | ▪ Phase records the exception.<br>▪ Phase is completed automatically. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 5.4.1.3 GID-2671485 Status transition failed (SR0311.3.2.2)

The **Status transition failed** exception is displayed automatically if a certain status transition could not be performed based on the given graph purpose and trigger.

The potential reasons for a failed status transition are:

- Source status does not match.

- Condition cannot be fulfilled or is not unique (in case of multiple transition definitions per trigger).

- Error during condition evaluation.

- Error during action evaluation.

The exception either applies to a single entity or to a main parent entity and to all of its child entities, respectively.

Representation of the exception:

Exception dialog

- \<Exception text\>
  (taken from **Status transition failed (SR0311.8.6)** process parameter (GID-2671482))

- In case of a single equipment entity:
  \<the reason that applies\>

- In case of an entity group:
  <the reasons that apply>

- List of potential reasons:

  - Cannot find the selected trigger.

  - Cannot find a transition for the current status.

  - Cannot find a fulfillable transition condition for the current status.

  - There is more than one fulfillable transition condition available for the current status: <TR-ID; TR-ID; ...>.

  - Cannot evaluate the transition condition (<TR-ID>).

  - Cannot evaluate the transition action (<TR-Action ID>) from the current status to the new status (<display text (key)>).

Exception Window

- <Exception text>
  (taken from **Status transition failed (SR0311.8.6)** process parameter (GID-2671482))
  (Information is provided for each entity for which a transition fails)
  <reason>
  Equipment: <equipment identifier> / <equipment short description>
  Equipment type: <list of equipment types> (if available)
  Graph (ID): <graph display text> (<identifier>)
  Purpose: <purpose>
  Current status (key): <display text> (<key>)
  Failed trigger (key): <display text> (<key>)

  - Example:
    Status transition failed.
    Cannot find a transition for the current status.
    Equipment: IBC0033
    Equipment type: Container (RS)
    Graph (ID): IBC Cleaning (IBCCleaning01)
    Purpose: Container Cleaning (RS)
    Current status (key): Blocked (BLOCKED)
    Failed trigger (key): In use (IN_USE)

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 5.4.1.4 GID-2671486 Status transition failed - Logic (SR0311.3.2.2.1)

- Trigger: The trigger could not be performed on the entity with the equipment graph and the given purpose.

- Postcondition: Exception is recorded and phase is completed

| Step | # | Description |
|------|---|-------------|
| Operator accepts exceptional situation | 1-10 | Phase shows exception description to be signed. |
| Operator signs exception | 1-20 | <ul><li>Phase records the exception.</li><li>In case of an entity group and if any transition fails, none of the transitions are performed at all.</li><li>Phase is completed automatically.</li></ul> |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 5.4.2 User-triggered Exceptions

There are no user-triggered exceptions available.

### 5.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

## 5.5 Information Messages

There are no information messages available.

## 5.6 Questions

There are no questions available.

## 5.7 Decisions

There are no decisions available.

## 5.8 Error Messages (SR0311.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

### 5.8.1 GID-2669573 No trigger selected (SR0311.3.6.1)

| UI text | Comment |
|---|---|
| You have to select a trigger before you can confirm. | Message pack: PhaseEqmEqTriggerTrans<version><br>Message ID: HintUserSelectionRequired_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Medium |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 5.8.2 GID-2669574 Entity not available (SR0311.3.6.2)

| UI text | Comment |
|---|---|
| Cannot find the expected entity. | Message pack: PhaseEqmEqTriggerTrans<version><br>Message ID: IdentifiedEquipmentNull_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 5.8.3 GID-2669575 Entity not main parent (SR0311.3.6.6)

| UI text | Comment |
|---|---|
| The <identifier> entity is a member of a group, but not its main parent. | Message pack: PhaseEqmEqTriggerTrans<version><br>Message ID: "IdentifiedEquipmentIsASubgroup_Error" |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 5.8.4 GID-2669576 Graph with purpose not assigned to entity (SR0311.3.6.3)

| UI text | Comment |
|---|---|
| The <identifier> entity does not hold an equipment graph of the <purpose> purpose. | In case of a single equipment entity:<br>Message pack: PhaseEqmEqTriggerTrans<version><br>Message ID: NoStatusGraphAssignedForPurpose_ErrorMsg |
| None of the entities of the <identifier> entity group holds an equipment graph of the <purpose> purpose. | In case of an entity group:<br>Message pack: PhaseEqmEqTriggerTrans<version><br>Message ID:<br>NoStatusGraphAssignedForPurposeOnGroup_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Medium |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 5.8.5 GID-2669577 No trigger available (SR0311.3.6.4)

| UI text | Comment |
|---|---|
| No purpose or trigger available. | Message pack: PhaseEqmEqTriggerTrans<version><br>Message ID: NoPurposeOrTriggerConfigured_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 5.9 Output Variables (SR0311.9+)

The following output variables are available to reference the phase's output.

### 5.9.1 Instance count (Framework capability)

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

### 5.9.2 Start time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

### 5.9.3 Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

### 5.9.4 Identifier (Framework capability)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

### 5.9.5 GID-2669582 Trigger execution successful (SR0311.9.1)

- Data type: Boolean

- Values: true, false

- Usage: The output variable states if the result of the equipment graph trigger execution was successful.

- The value is true if the graph transition with the selected trigger has been executed successfully.

- The value is false if the phase is completed with an exception.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 5.9.6 GID-2669583 Graph (SR0311.9.2)

- Data type: String

- Usage: The output variable provides the identifier of the used equipment graph.
  It applies to a single entity or to a main parent entity; it does not represent the graph of a child entity.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 5.9.7  GID-2669584 Selected trigger (SR0311.9.3)

- Data type: String

- Usage: The output variable provides the trigger (key) of the used equipment graph.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 5.9.8  GID-2669585 Old status (SR0311.9.4)

- Data type: String

- Usage: The output variable provides the old status (key) of the equipment entity.
  It applies to a single entity or to a main parent entity; it does not represent the status of a child entity.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 5.9.9  GID-2669586 New status (SR0311.9.5)

- Data type: String

- Usage: The output variable provides the new status (key) of the equipment entity.
  It applies to a single entity or to a main parent entity. It does not represent the status of a child entity.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

# 6 Separate Equipment Phase (SR0312+)

The **Separate equipment** phase allows an operator to separate an equipment entity group. Either the entire group is separated into single entities or a single entity or a sub-group is separated from a main group.
Based on the phase configuration, a separated equipment entity can keep its binding status and a separated sub-group can keep its grouping by retaining its relations to its own child entities.

An example use case is:

- Need to separate a coater before cleaning
  A coater has to be separated into single equipment entities to run specific cleaning processes for different parts.

The affected equipment entities are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669589).

Anomalies that occur during processing are covered by the phase exception handling (GID-2668300)(e.g. skip separation).

After completion the phase displays the affected equipment entities with their identifiers and short descriptions in the Execution Window.

The Navigator displays the identifier of the parent equipment entity and the equipment entity to be separated (if applicable).



Remove the feeder seal from the tablet press.

| | |
|---|---|
| Parent entity of group: | TabletPress_AM / Automated Tablet Press |
| Entity to be separated: | TabletPressFeederSeal / Feeder Seal for Automated Tablet Press |
| Keep sub-group: | No |
| Keep binding: | No |

Entities to be separated

| Identifier | Short description |
|---|---|
| TabletPressFeederSeal | Feeder Seal for Automated Tablet Press |

Confirm

*Figure 16: Separate equipment (single entity) during execution*

Remove the feeder group from the tablet press.

Parent entity of group:     TabletPress_AM / Automated Tablet Press
Entity to be separated:     TabletPressFeeder / Feeder for Automated Tablet Press
Keep sub-group:             Yes
Keep binding:               No

Entities to be separated

| Identifier | Short description |
|---|---|
| TabletPressFeeder | Feeder for Automated Tablet Press |
| TabletPressFeederSeal | Feeder Seal for Automated Tablet Press |

Confirm

*Figure 17: Separate equipment (single entity) during execution*

Disassemble the tablet press.

Parent entity of group:     TabletPress_AM / Automated Tablet Press
Keep sub-group:             No
Keep binding:               No

Entities to be separated

| Identifier | Short description |
|---|---|
| TabletDischargeChute | Discharge chute for Automated Tablet Press |
| TabletPressFeeder | Feeder for Automated Tablet Press |
| TabletPressFeederSeal | Feeder Seal for Automated Tablet Press |

Confirm

*Figure 18: Separate equipment (single entity) during execution*

## 6.1 Layout

The phase provides individual layouts for its representation during execution, (GID-2669538)in the Navigator, (GID-2669539)and in the sub-report (GID-2669540).

### 6.1.1 Representation during Execution (SR0312.1+)

The representation during execution depends on the phase mode.

#### 6.1.1.1 GID-2671487 PREVIEW MODE (SR0312.1.1)

1. <Instruction text>
   (taken from **Instruction (SR0312.8.1)** process parameter (GID-2671499))

2. Parent entity of group:

3. Keep sub-group: <Yes/No>
   (taken from **Keep defined sub-group (SR0312.8.9)** process parameter (GID-2671504))

4. Keep binding: <Yes/No>
   (taken from **Keep binding (SR0312.8.10)** process parameter (GID-2671505))

5. List of child entities to be separated from the group:

   ▪ Only if the **Show children (SR0320.8.4)** process parameter (GID-2671525)is set to **Yes**.

6. **Confirm** button (disabled).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Medium |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 6.1.1.2 GID-2671488 ACTIVE MODE (SR0312.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0312.8.1)** process parameter (GID-2671499))

3. Parent entity of group: <parent entity identifier> / <parent entity short description>
   (taken from **Parent entity of group (SR0312.8.2)** process parameter (GID-2671500))

4. Entity to be separated: <equipment entity identifier> / <equipment entity short description>
   (taken from **Child entity to be separated (SR0312.8.5)** process parameter (GID-2671501))>

   ▪ Only if the **Child entity to be separated (SR0312.8.5)** process parameter (GID-2671501)is
   not null.

5. Keep sub-group: <Yes/No>
   (taken from **Keep defined sub-group (SR0312.8.9)** process parameter (GID-2671504))

6. Keep binding: <Yes/No>
   (taken from **Keep binding (SR0312.8.10)** process parameter (GID-2671505))

7. List of child entities to be separated from the group:

   ▪ Only if the **Show children (SR0320.8.4)** process parameter (GID-2671525)is set to **Yes**.

   ▪ Details of child entity.

| <Child entity identifier> | <Child entity short description> |
|---|---|

8. **Confirm** button.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 6.1.1.3 GID-2671489 COMPLETED MODE (SR0312.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0312.8.1)** process parameter (GID-2671499))

3. Parent entity of group: <parent entity identifier> / <parent entity short description>
   (taken from **Parent entity of group (SR0312.8.2)** process parameter (GID-2671500))

4. Separated entity: <equipment entity identifier> / <equipment entity short description>
   (taken from **Child entity to be separated (SR0312.8.5)** process parameter (GID-2671501))

   ▪ Only if the **Child entity to be separated (SR0312.8.5)** process parameter (GID-2671501)is not null.

5. Keep sub-group: <Yes/No>
   (taken from **Keep defined sub-group (SR0312.8.9)** process parameter (GID-2671504))

6. Keep binding: <Yes/No>
   (taken from **Keep binding (SR0312.8.10)** process parameter (GID-2671505))

7. List of child entities that were separated from the group:

   ▪ Only if the **Show children (SR0320.8.4)** process parameter (GID-2671525)is set to **Yes**.

     ▪ Details of child entity.

| <Child entity identifier> | <Child entity short description> |
|---|---|

8. **Confirm** button (completed).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 6.1.2 Representation in Navigator (SR0312.4+)

The Navigator provides the following details:

### 6.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

▪ <Phase name>

  ▪ Example:
    Separate coater

### 6.1.2.2 GID-2671491 INFORMATION COLUMN (SR0312.4.1)

- <Identifier of parent equipment entity>

    - Example: CompactorC33

- Only if the **Child entity to be separated (SR0312.8.5)** process parameter (GID-2671501)is not null.

    - <Identifier of parent equipment entity>
      <Identifier of child equipment entity>

        - Example:
          CompactorC33
          CompactorCrusher01

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Low |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 6.1.2.3 ACTION COLUMN

- There are no actions available.

## 6.1.3 Representation in Sub-report (SR0312.5+)

The sub-report contains the following information:

### 6.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>

- <Completion time>

- <Unit procedure> / <operation> / <phase>

- <Work center> / <station> / <device> - <phase completion user>

### 6.1.3.2 GID-2671494 SUB-REPORT ELEMENTS (SR0312.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Instruction text

- Group parent entity: <parent entity identifier> / <parent entity short description>

- Separated entity: <equipment entity identifier> / <equipment entity short description>

    - Only if the **Child entity to be separated (SR0312.8.5)** process parameter (GID-2671501)is not null.

    - Binding kept <Yes/No>

- Defined sub-group kept <Yes/No>

- List of separated child entities (identifier and short description) that were separated from the group

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 6.2 Business Logic (SR0312.2+)

The phase implements the following business logic.

### 6.2.1 GID-2669590 Separate a group (SR0312.2.1)

- Function: Separate equipment entities from a group

- Trigger: Phase becomes active

- Postcondition: Equipment entities are no longer grouped

| Step | # | Description |
|---|---|---|
| Phase activation | 10 | Phase displays its user interface according to the **Active mode (SR0312.1.2)** layout (GID-2671488). |
| Phase checks availability of parent entity definition | 20 | If the **Parent entity of group (SR0312.8.2)** process parameter (GID-2671500)is null, phase displays the **Parent entity of group not defined (SR0312.3.6.3)** error message (GID-2669600). |
| Phase checks that parent entity is main parent entity | 30 | If the entity defined with the **Parent entity of group (SR0312.8.2)** process parameter (GID-2671500)is not a main parent entity:<br><br>- Phase displays the **Not main parent (SR0312.3.6.2)** error message (GID-2669599). |
| Phase checks parent-child relationship of referenced equipment entities | 40 | If the entity defined with the **Child entity to be separated (SR0312.8.5)** process parameter (GID-2671501)is not member of the group defined with the **Parent entity of group (SR0312.8.2)** process parameter (GID-2671500):<br><br>- Phase displays the **Not part of group (SR0312.3.6.1)** error message (GID-2669598).<br><br>(It is not necessary that the **child entity to be separated** is a direct child of the **parent entity of group**.) |

| Step | # | Description |
|------|---|-------------|
| Phase checks the completion mode | 50 | If all checks have passed successfully, phase continues as follows:<br>▪ **Mode (SR0312.8.3)** process parameter (GID-2671502)is set to **Manual completion**:<br>Phase continues with the next step upon phase confirmation by the operator.<br>▪ **Mode (SR0312.8.3)** process parameter (GID-2671502)is set to **Automatic completion**:<br>Phase automatically continues with the next step. |
| Phase **separates** equipment entities **completely** | 70.1 | If the **Child entity to be separated (SR0312.8.5)** process parameter (GID-2671501)is null and the **Keep sub-group (SR0312.8.9)** process parameter (GID-2671504)is set to **No**:<br>▪ Phase completely separates the group defined with the **Parent entity of group (SR0312.8.2)** process parameter (GID-2671500), including all of its sub-groups (if available).<br>▪ Example: Scenario 1 in figure "Separate equipment scenarios" (GID-2669514). |
| Phase **separates** equipment entities **partially** | 70.2 | If the **Child entity to be separated (SR0312.8.5)** process parameter link is null and the **Keep sub-group (SR0312.8.9)** process parameter (GID-2671504) is set to **Yes**:<br>▪ Phase separates all direct child entities from the **parent entity of group**, but keeps all sub-groups (if applicable).<br>▪ Example: Scenarios 2 and 3 in figure "Separate equipment scenarios" (GID-2669514).<br>If the **Child entity to be separated (SR0312.8.5)** process parameter (GID-2671501)is not null:<br>▪ Phase separates the **child entity to be separated** from its direct parent (which is not necessarily the main parent according to the **Parent entity of group (SR0312.8.2)** process parameter (GID-2671500)).<br>▪ If the **Keep sub-group (SR0312.8.9)** process parameter (GID-2671504)is set to **Yes**:<br>Phase keeps all sub-groups of the separated entity (if applicable).<br>▪ Example: Scenarios 4 and 5 in figure "Separate equipment scenarios" link.<br>▪ If the **Keep sub-group (SR0312.8.9)** process parameter (GID-2671504)is set to **No**:<br>Phase separates all sub-groups of the separated entity (if applicable).<br>▪ Example: Scenario 6 in figure "Separate equipment scenarios" (GID-2669514). |
| | 70.3 | If the separation of entities was successful, the logbooks of parent and child equipment entities are updated accordingly (if maintained). |

| Step | # | Description |
|------|---|-------------|
| Phase handles binding status | 80 | If the **Keep binding (SR0312.8.10)** process parameter (GID-2671505)is set to **No**:<br><br>• For all separated equipment entities and sub-groups, phase resets binding status of each entity to **Available** and updates the binding context in the **Context** tab of the equipment entity (not for workflows) and the logbooks accordingly (Unbind) (if maintained).<br>• Example: Scenarios 1, 5, and 6 in figure "Separate equipment scenarios" (GID-2669514).<br><br>If the **Keep binding (SR0312.8.10)** process parameter (GID-2671505)is set to **Yes**:<br><br>• For all separated equipment entities and sub-groups, phase keeps the current binding status of each entity.<br>• Example: Scenarios 3 and 4 in figure "Separate equipment scenarios" (GID-2669514). |
| | 90 | In case an error has occurred during separation, phase displays the **Equipment separation failed (SR0312.3.6.4)** error message (GID-2669601).<br><br>In case an error has occurred during unbinding, phase displays the **Equipment unbinding (SR0312.3.6.5)** error message (GID-2669602).<br><br>In case of an error, all already executed separation or unbinding actions are undone.<br><br>In case no error has occurred, phase is completed automatically. |
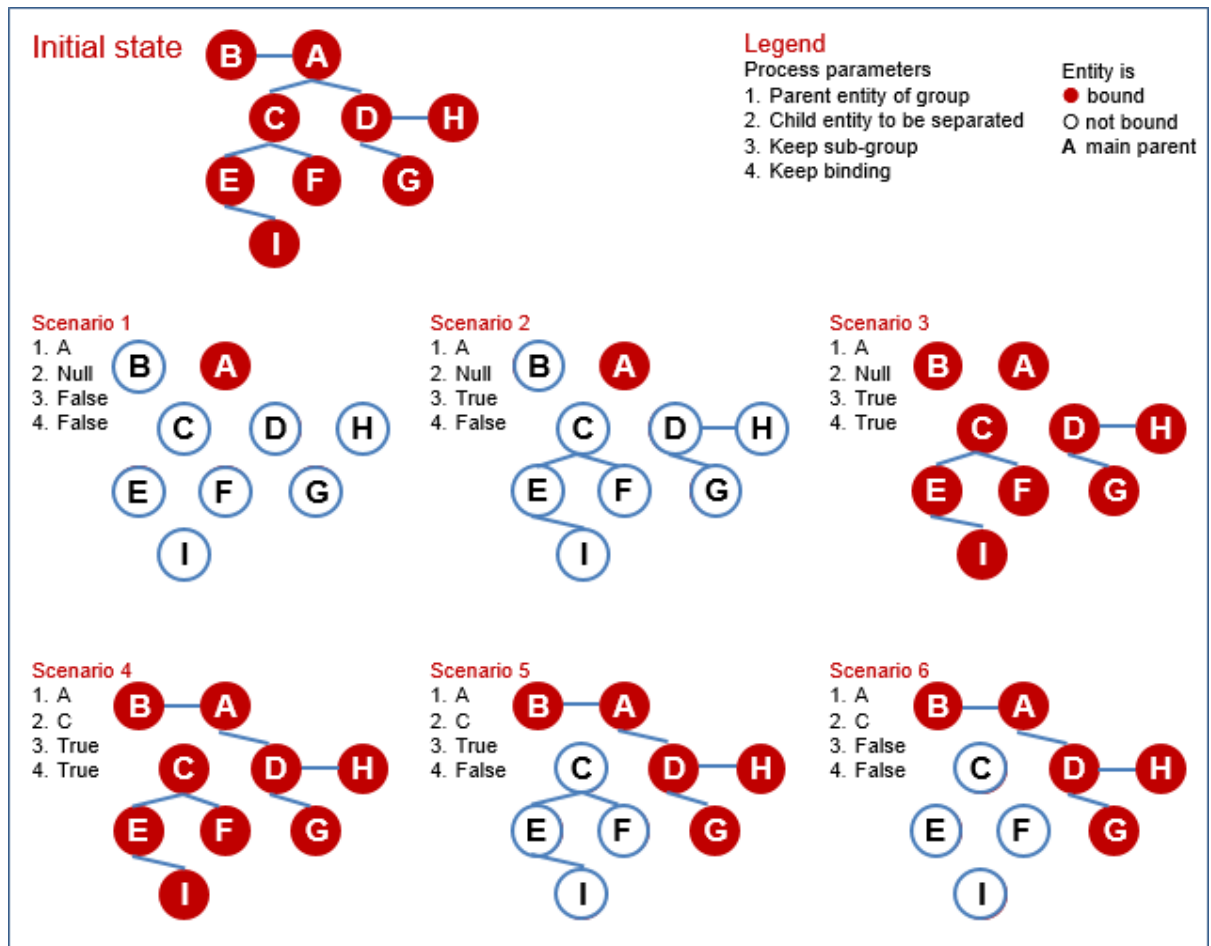
*Figure 19: Separate equipment scenarios*

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 6.3  Process Parameters (SR0312.8+)

The following process parameters define the behavior of the phase.

### 6.3.1  Instruction Table-specific Parameters

#### 6.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Table layout | Choice list | Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**. |
| First column narrow | Boolean | Defines if the first column of the table shall be narrow. |
| Show all borders | Boolean | Defines if the borders of the table shall be visible. |

#### 6.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Column 1 | HTML text | Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags). |
| Column 2 | HTML text | |
| Column 3 | HTML text | |
| Column 4 | HTML text | |
| Column 5 | HTML text | |

### 6.3.2 Instruction Link-specific Parameters

#### 6.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Instruction text | HTML text | Instruction text to be displayed.<br>For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671498).<br>Example: Refer to {SOP1270} for guidance.<br><br>Maximum length is 2000 characters (including HTML tags). |

#### 6.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Link text | Text | Text to be used as link.<br>For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute.<br>Including the brackets in the link text is optional.<br><br>Maximum length is 80 characters. |
| Link URL | Text | URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system.<br><br>Maximum length is 256 characters. |

### 6.3.3 Basic Parameters

#### 6.3.3.1 GID-2671499 INSTRUCTION (SR0312.8.1)

| Attribute | Type | Comment |
|---|---|---|
| Text | HTML text | Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags). |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 6.3.3.2 GID-2671500 PARENT ENTITY OF GROUP (SR0312.8.2)

| Attribute | Type | Comment |
|---|---|---|
| Equipment object | Reference | Reference to the equipment object output variable of a preceding phase that provides the main parent entity of a group. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 6.3.3.3 GID-2671501 CHILD ENTITY TO BE SEPARATED (SR0312.8.5)

| Attribute | Type | Comment |
|---|---|---|
| Equipment object | Reference | Optional. Reference to the equipment object output variable of a preceding phase that provides the child entity to be separated from a group. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 6.3.3.4 GID-2671502 MODE (SR0312.8.3)

| Attribute | Type | Comment |
|---|---|---|
| Mode | Choice list | Defines the processing mode.<br>**Manual completion** (default): Operator confirms the phase.<br>**Automatic completion**: Phase automatically separates the equipment entities and is completed. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 6.3.3.5 GID-2671503 SHOW CHILDREN (SR0312.8.4)

| Attribute | Type | Comment |
|---|---|---|
| Enabled | Boolean | Controls if the list of child entities that are separated is displayed during execution.<br>Default setting: **Yes** |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 6.3.3.6 GID-2671504 KEEP SUB-GROUP (SR0312.8.9)

| Attribute | Type | Comment |
|---|---|---|
| Enabled | Boolean | Controls if any sub-groups (if applicable) of a separated entity are kept. If not, all sub-groups of the separated entity are completely separated as well.<br>Default setting: **Yes** |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 6.3.3.7 GID-2671505 KEEP BINDING (SR0312.8.10)

| Attribute | Type | Comment |
|---|---|---|
| Enabled | Boolean | Controls if separated entities or sub-groups keep their binding status. If not, they are unbound along with the separation.<br>Default setting: **Yes** |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 6.3.4 Configuration of User-triggered Exceptions

### 6.3.4.1 GID-2671506 SKIP SEPARATION (SR0312.8.8)

| Attribute | Type | Comment |
|---|---|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.<br>Available settings: **None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).**<br>Default setting: **High.** |
| Exception text | Text | Defines the exception description used during exception handling and within the batch record.<br>Maximum length is 250 characters. |

See also **Skip separation (SR0312.3.1.1)** user-triggered exception (GID-2671508).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 6.4 Exceptions (SR0312.3+)

The phase supports user-defined, user-triggered (GID-2669596), system-triggered (GID-2669595), and post-completion exceptions (GID-2669597)and their configuration by means of process parameters (GID-2668299).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

### 6.4.1 System-triggered Exceptions

There are no system-triggered exceptions available.

### 6.4.2 User-triggered Exceptions (SR0312.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

#### 6.4.2.1 GID-2671507 SKIP SEPARATION (SR0312.3.1.1)

The **Skip separation** exception allows an operator to skip the phase in order to pass an error situation. This may require the separation process to be performed in Data Manager [A3] (GID-2667997).

Representation during exception handling:

▪ Instruction:
   Skip the separation.
   **Confirm** button.

▪ Exception text:
   <Exception text>
   (taken from **Skip separation (SR0312.8.8)** process parameter (GID-2671506))
   Parent entity: <identifier of parent equipment entity>
   Child entity: <identifier of child equipment entity>

   (If an entity is not available or not configured, phase displays "N/A" as identifier.)

   ▪ Example:
      Separation has been skipped.
      Parent entity: CompactorC33
      Child entity: CompactorCrusher01

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 6.4.2.2 GID-2671508 SKIP SEPARATION - LOGIC (SR0312.3.1.1.1)

- Trigger: Exception is selected

- Postcondition: **Separate equipment** phase is skipped

| Step | # | Description |
|------|---|-------------|
| Operator confirms exception | 10 | Phase shows exception description to be signed according to **Skip separation (SR0312.8.8)** process parameter (GID-2671506). |
| Operator signs exception | 20 | ▪ Phase records the exception.<br>▪ Phase is completed automatically. |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 6.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

## 6.5 Information Messages

There are no information messages available.

## 6.6 Questions

There are no questions available.

## 6.7 Decisions

There are no decisions available.

## 6.8 Error Messages (SR0312.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

### 6.8.1 GID-2669598 Not part of group (SR0312.3.6.1)

| UI text | Comment |
|---|---|
| The <child entity identifier> entity that is to be separated from the group is no child of the defined group (<parent entity identifier>). | Message pack: PhaseEqmEqSeparate<version><br>Message ID: ChildEntityNotPartOfGroup_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 6.8.2 GID-2669599 Not main parent (SR0312.3.6.2)

| UI text | Comment |
|---|---|
| Cannot perform the separation, since the <parent entity identifier> entity is not the main parent of the group. | Message pack: PhaseEqmEqSeparate<version><br>Message ID: NotRootEntity_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 6.8.3 GID-2669600 Parent entity of group not defined (SR0312.3.6.3)

| UI text | Comment |
|---|---|
| There is no parent entity of the group defined. | Message pack: PhaseEqmEqSeparate<version><br>Message ID: NoRootEntity_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Medium |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### *6.8.4 GID-2669601 Equipment separation failed (SR0312.3.6.4)*

| UI text | Comment |
|---|---|
| An error has occurred while separating the <entity identifier> entity from its group. | Message pack: PhaseEqmEqSeparate<version><br>Message ID: SeparationFailed_ErrorMsg<br><br>The **Details** button provides access to more specific information about the error. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### *6.8.5 GID-2669602 Equipment unbinding failed (SR0312.3.6.5)*

| UI text | Comment |
|---|---|
| An error has occurred while unbinding the <entity identifier> entity. | Message pack: PhaseEqmEqSeparate<version><br>Message ID: ReleaseFailed_ErrorMsg<br><br>The **Details** button provides access to more specific information about the error and the entities that cause the error. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 6.9 Output Variables (SR0310.9+)

The following output variables are available to reference the phase's output.

### *6.9.1 Instance count (Framework capability)*

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

### *6.9.2  Start time (Framework capability)*

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

### *6.9.3  Completion time (Framework capability)*

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

### *6.9.4  Identifier (Framework capability)*

- Data type: String

- Usage: The output variable provides the identifier of the phase.

# 7   Unbind Equipment Phase (SR0320+)

The **Unbind equipment** phase allows an operator to release a previously bound equipment entity or all equipment entities of a group before a unit procedure is finished. Thus, the entity or entity group can be identified within another unit procedure context while the current unit procedure is still running.

Example use cases are:

- Need to explicitly unbind an equipment entity.
  A measuring tool needs to be used in multiple orders that run in parallel. It must be released from one order prior to the automatic release along with order step finish. Once released, it can again be identified and used in a different order.

- Need to explicitly unbind an equipment group
  Cleaning of a used machine with all of its components has to be started before the current order step is completed. The machine can be unbound as soon as it is no longer used in the context of the current order step.

The affected equipment entities are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669609).

Anomalies that occur during processing are covered by the phase exception handling (GID-2668309)(e.g. equipment entity is not available).

After completion the phase displays the affected (parent) equipment entity and the child entities (if applicable) with their identifiers and short descriptions in the Execution Window.

The Navigator displays the identifier of the affect (parent) equipment entity and the number of child entities (if applicable).



*Figure 20: Unbind equipment during execution*

*Figure 21: Unbind equipment during execution*

## 7.1 Layout

The phase provides individual layouts for its representation during execution (GID-2669607), in the Navigator (GID-2669608), and in the sub-report (GID-2669609).

### 7.1.1 Representation during Execution (SR0320.1+)

The representation during execution depends on the phase mode.

#### 7.1.1.1 GID-2671509 PREVIEW MODE (SR0320.1.1)

1. <Instruction text>
   (taken from **Instruction (SR0320.8.1)** process parameter (GID-2671521))

2. Entity:

3. List of child entities of

   ▪ Only if the **Show children (SR0320.8.6)** process parameter (GID-2671524)is set to **Yes**.

4. **Confirm** button (disabled).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Medium |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 7.1.1.2 GID-2671510 ACTIVE MODE (SR0320.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0320.8.1)** process parameter (GID-2671521))

3. Entity: <equipment entity identifier> / <equipment entity short description>
   (taken from **Identified equipment entity (SR0320.8.2)** process parameter (GID-2671522))

4. List of child entities of <equipment entity identifier> / <equipment entity short description>
   (taken from **Identified equipment entity (SR0320.8.2)** process parameter (GID-2671522))

- Only in case of an entity group and if the **Show children (SR0320.8.6)** process parameter (GID-2671524)is set to **Yes**.

- Details of child entity.

| <Child entity identifier> | <Child entity short description> |
|---|---|

5. **Confirm** button.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 7.1.1.3 GID-2671511 COMPLETED MODE (SR0320.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0320.8.1)** process parameter (GID-2671521))

3. Entity: <equipment entity identifier> / <equipment entity short description>
   (taken from **Identified equipment entity (SR0320.8.2)** process parameter (GID-2671522))

4. List of child entities of <equipment entity identifier> / <equipment entity short description>
   (taken from **Identified equipment entity (SR0320.8.2)** process parameter (GID-2671522))

   - Only in case of an entity group and if the **Show children (SR0320.8.6)** process parameter (GID-2671524)is set to **Yes**.

   - Details of child entity.

| <Child entity identifier> | <Child entity short description> |
|---|---|

5. **Confirm** button (completed).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 7.1.2 Representation in Navigator (SR0320.4+)

The Navigator provides the following details:

#### 7.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>

  - Example:
    Unbind blender

#### 7.1.2.2 GID-2671513 INFORMATION COLUMN (SR0320.4.1)

- <Identifier of affected equipment entity>

  - Example: BlenderA12

  - Only in case of an entity group

  - <Identifier of affected equipment entity>
    <Number of child entities> child entities

    - Example:
      BlenderA12
      5 child entities

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Low |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 7.1.2.3 ACTION COLUMN

- There are no actions available.

### 7.1.3 Representation in Sub-report (SR0320.5+)

The sub-report contains the following information:

#### 7.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>

- <Completion time>

- <Unit procedure> / <operation> / <phase>

- <Work center> / <station> / <device> - <phase completion user>

### 7.1.3.2 GID-2671516 Sub-report elements (SR0320.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Instruction text

- Entity <equipment entity identifier> / <equipment entity short description>
  (taken from **Identified equipment entity (SR0320.8.2)** process parameter (GID-2671522))

- **List of child entities** (If the equipment entity is the main parent of a group, the list of its child entities is added to the report.):

| Identifer | Short description |
|---|---|
| <Child entity identifier> | <Child entity short description> |
| ... | ... |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 7.2 Business Logic (SR0320.2+)

The phase implements the following business logic.

### 7.2.1 GID-2669610 Unbind equipment entity (SR0320.2.1)

- Function: Unbind affected equipment entities

- Trigger: Phase becomes active

- Postcondition: Equipment entities are no longer bound

| Step | # | Description |
|---|---|---|
| Phase activation | 10 | Phase displays its user interface according to the **Active mode (SR0320.1.2)** layout (GID-2671510). |
| Phase checks the completion mode | 20 | - **Mode (SR0320.8.3)** process parameter (GID-2671523) is set to **Manual completion:** Phase continues with the next step upon phase confirmation by the operator.<br>- **Mode (SR0320.8.3)** process parameter (GID-2671523) is set to **Automatic completion:** Phase automatically continues with the next step. |

| Step | # | Description |
|------|---|-------------|
| Phase checks if the referenced equipment entity or entity group is available at runtime | 30 | • If no equipment entity is referenced, phase creates the **Equipment data mismatch (SR0320.3.2.1)** system-triggered exception (GID-2671527).<br>• If the equipment entity is member of a group, but not the main parent entity, phase creates the **Equipment data mismatch (SR0320.3.2.1)** system-triggered exception (GID-2671527).<br>If the check passes successfully, phase continues with the next check. |
| Phase checks if all entities are bound | 40 | The following checks either apply to a single entity or to a main parent entity and to all of its child entities, respectively:<br>• If any equipment entity is not bound, phase creates the **Equipment unbind failed (SR0320.3.2.2)** system-triggered exception (GID-2671529).<br>• If any equipment entity is bound to a different unit procedure context, phase creates the **Equipment unbind failed (SR0320.3.2.2)** system-triggered exception (GID-2671529).<br>If the check passes successfully, phase continues with the next check. |
| Phase resets the status of the equipment entity or entity group to **Available** | 50 | • If a system-triggered exception has been recorded, phase does not change the binding status of any equipment.<br>• If the binding status of all equipment entities can be set to **Available**, the binding context in the **Context** tab of the equipment entity (not for workflows) and the logbook of all entities is updated accordingly (Unbind) (if maintained) and phase is completed. |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 7.3  Process Parameters (SR0320.8+)

The following process parameters define the behavior of the phase.

### 7.3.1  Instruction Table-specific parameters

#### 7.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Table layout | Choice list | Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**. |
| First column narrow | Boolean | Defines if the first column of the table shall be narrow. |
| Show all borders | Boolean | Defines if the borders of the table shall be visible. |

#### 7.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Column 1 | HTML text | Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags). |
| Column 2 | HTML text | |
| Column 3 | HTML text | |
| Column 4 | HTML text | |
| Column 5 | HTML text | |

### 7.3.2 Instruction Link-specific Parameters

#### 7.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Instruction text | HTML text | Instruction text to be displayed.<br>For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671520).<br>Example: Refer to {SOP1270} for guidance.<br><br>Maximum length is 2000 characters (including HTML tags). |

#### 7.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Link text | Text | Text to be used as link.<br>For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute.<br>Including the brackets in the link text is optional.<br><br>Maximum length is 80 characters. |
| Link URL | Text | URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system.<br><br>Maximum length is 256 characters. |

### 7.3.3  Basic Parameters

#### 7.3.3.1 GID-2671521 INSTRUCTION (SR0320.8.1)

| Attribute | Type | Comment |
|-----------|------|---------|
| Text | HTML text | Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags). |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 7.3.3.2 GID-2671522 IDENTIFIED EQUIPMENT ENTITY (SR0320.8.2)

| Attribute | Type | Comment |
|-----------|------|---------|
| Equipment object | Reference | Reference to the output of a preceding phase that provides an identified equipment entity. |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 7.3.3.3 GID-2671523 MODE (SR0320.8.3)

| Attribute | Type | Comment |
|-----------|------|---------|
| Mode | Choice list | Defines the processing mode. **Manual completion** (default): Operator confirms the phase. **Automatic completion**: Phase automatically unbinds the equipment entities and is completed. |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 7.3.3.4 GID-2671524 Show children (SR0320.8.6)

| Attribute | Type | Comment |
|-----------|------|---------|
| Enabled | Boolean | Controls if the list of child entities is displayed during execution.<br>Default setting: **Yes** |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 7.3.4 Configuration of System-triggered Exceptions

### 7.3.4.1 GID-2671525 Equipment data mismatch (SR0320.8.4)

| Attribute | Type | Comment |
|-----------|------|---------|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.<br>Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**.<br>Default setting: **High**. |
| Exception text | Text | Defines the exception description used during exception handling and within the batch record.<br>Maximum length is 250 characters. |

See also **Equipment data mismatch - Logix (SR0320.3.2.1.1)** system-triggered exception (GID-2671528).

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 7.3.4.2 GID-2671526 EQUIPMENT UNBIND FAILED (SR0320.8.5)

| Attribute | Type | Comment |
|-----------|------|---------|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.<br>Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**.<br>Default setting: **High**. |
| Exception text | Text | Defines the exception description used during exception handling and within the batch record.<br>Maximum length is 250 characters. |

See also **Equipment unbind failed (SR0320.3.2.2)** system-triggered exception (GID-2671529).

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 7.4 Exceptions (SR0320.3+)

The phase supports user-defined, user-triggered (GID-2669616), system-triggered (GID-2669615), and post-completion exceptions (GID-2669617)and their configuration by means of process parameters (GID-2668308).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

### 7.4.1 System-triggered Exceptions (SR0320.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

### 7.4.1.1 GID-2671527 EQUIPMENT DATA MISMATCH (SR0320.3.2.1)

The exception text is extended by messages specific to the current situation.

Representation of the exception:

- &lt;Exception text&gt;
  (taken from **Equipment data mismatch (SR0320.8.4)** process parameter (GID-2671525))

- If the expected equipment is not available:
  Cannot find the expected entity.

- If the expected equipment entity is member of a group, but not the main parent entity:
  The <entity identifier> entity is only a member and not the main parent of the group (<parent entity identifier>).

- Example:
  Equipment data configuration error.
  The Hose047 entity is only a member and not the main parent of the group (Compactor-base).

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 7.4.1.2 GID-2671528 EQUIPMENT DATA MISMATCH - LOGIC (SR0320.3.2.1.1)

- Trigger: Equipment entity or entity status do not match

- Postcondition: Exception is recorded

| Step | # | Description |
|------|---|-------------|
| Operator triggers exception | 10 | Phase records the exception. |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 7.4.1.3 GID-2671529 EQUIPMENT UNBIND FAILED (SR0320.3.2.2)

The exception text is extended by messages specific to the current situation.

Representation of the exception:

Exception dialog

- <Exception text>
  (taken from **Equipment unbind failed (SR0320.8.5)** process parameter (GID-2671526))

  - If a single equipment entity is not in the **Bound** status:
    The <entity identifier> entity is not bound.

  - If a single equipment entity is bound within a different unit procedure context:
    Cannot unbind the <entity identifier> entity.
    Cannot unbind the <entity identifier> equipment entity here, since it has already been

identified or bound at the <work center identifier> work center for <process order or workflow identifier> (unit procedure: <unit procedure identifier>, operation: <operation identifier>, phase: <phase identifier>).

- If any equipment entity of a group is not in the **Bound** status or bound within a different unit procedure context:
  Unbind of <identifier of main parent entity> failed.

Exception Window

- <Exception text>
  (taken from **Equipment unbind failed (SR0320.8.5)** process parameter [(GID-2671526)](GID-2671526))

  - If a single equipment entity is not in the **Bound** status:
    The <entity identifier> entity is not bound.

  - If a single equipment entity is bound within a different unit procedure context:
    Cannot unbind the <entity identifier> entity.
    Cannot unbind the <entity identifier> equipment entity here, since it has already been identified or bound at the <work center identifier> work center for <process order or workflow identifier> (unit procedure: <unit procedure identifier>, operation: <operation identifier>, phase: <phase identifier>).

- If any equipment entity of a group is not in the **Bound** status or bound within a different unit procedure context:
  Unbind of <identifier of main parent entity> failed.

  - For each equipment entity of the group, the following details are listed:
    Entity: <entity identifier>
    Reason: The entity is not bound.
    Entity: <entity identifier>
    Reason: Cannot unbind the <identifier> equipment entity here, since it has already been identified or bound at the <work center identifier> work center for <process order or workflow identifier> (unit procedure: <unit procedure identifier>, operation: <operation identifier>, phase: <phase identifier>).

    - Example:
      Unbind failed.
      Cannot unbind the BlenderA12 equipment entity.
      Cannot unbind the BlenderA12 equipment entity here, since it has already been identified or bound at the WKC_Processing work center for WF_Blender (unit procedure: UP-01, operation: OP-01, phase: PH-Release-Blender).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

### 7.4.1.4 GID-2671530 EQUIPMENT UNBIND FAILED - LOGIC (SR0320.3.2.2.1)

- Trigger: Unbind of equipment entity or of an equipment entity of a group failed

- Postcondition: Exception is recorded

| Step | # | Description |
|------|---|-------------|
| Operator triggers exception | 10 | Phase records the exception. |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | Yes |

## 7.4.2 User-triggered Exceptions

There are no user-triggered exceptions available.

## 7.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

## 7.5 Information Messages

There are no information messages available.

## 7.6 Questions

There are no questions available.

## 7.7 Decisions

There are no decisions available.

## 7.8 Error Messages

There are no error messages available.

## 7.9  Output Variables

The following output variables are available to reference the phase's output.

### 7.9.1  Instance count (Framework capability)

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

### 7.9.2  Start time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

### 7.9.3  Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

### 7.9.4  Identifier (Framework capability)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

# 8 Show Equipment List Phase (SR0305+)

The **Show equipment list** phase allows to show a list of equipment entities with the current values of a defined set of their specification properties and their runtime data, such as runtime properties and graph-related data.

Only equipment entities in an **Active** state (e.g. **Approved** ) are included in the list. The system, however can be configured to include other states. In case of a group of entities, only the parent entity is considered.

An example use case is:

- Support the operator in his decision which vessel to use in the next processing step depending on the status and the temperature of the entity.

The instruction text is stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669624).

Anomalies that occur during processing are covered by the phase exception handling (GID-2668318)(e.g. adding a user-defined exception).

After completion the phase displays the instruction text in the Execution Window.

The Navigator displays the beginning of the instruction text.



| Determine components to be sterilized. | | |
|---|---|---|
| Timestamp: 10/13/2022 03:18:12 PM CEST | | |
| Identifier | Unit Cleaning Graph (status) | Usage Counter |
| SterilizationTray-A | To be cleaned | 3 |
| TPFL-A-001 | To be cleaned | 3 |
| TabletDischargeChute-AS-A | To be cleaned | 3 |
| TabletPressFeeder-AS-A | To be cleaned | 3 |
| TabletPressFeederSeal-AS-A | To be cleaned | 3 |

*Figure 22: Show equipment list during execution*

## 8.1 Layout

The phase provides individual layouts for its representation during execution (GID-2669622), in the Navigator (GID-2669623), and in the sub-report (GID-2669624).

### 8.1.1 Representation during Execution (SR0305.1+)

The representation during execution depends on the phase mode.

#### 8.1.1.1 GID-2671531 PREVIEW MODE (SR0305.1.1)

1. <Instruction text>
   (taken from **Instruction (SR0305.8.1)** process parameter (GID-2671844))

2. No data loaded yet.

3. **Refresh** button (disabled)

4. List of equipment entities with the current values of the configured property types and equipment graphs
   (taken from **Equipment parameters (SR0305.6.1)** process input (GID-2671539)and **Column definition (SR0305.8.3)** process parameter (GID-2671846))

   ▪ Empty table.

5. **Confirm** button (disabled).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Medium |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 8.1.1.2 GID-2671532 ACTIVE MODE (SR0305.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0305.8.1)** process parameter (GID-2671844))

3. <Data reading timestamp>

4. **Refresh** button

5. List of equipment entities with the current values of the configured property types and equipment graphs
   (taken from **Equipment parameters (SR0305.6.1)** process input (GID-2671539)and **Column definition (SR0305.8.3)** process parameter (GID-2671846))

   ▪ 1st column: Equipment entity identifier

   ▪ 2nd - 9th column: Data

   ▪ For property types, the phase displays the identifier as column header and the current value as data.

   ▪ For equipment graphs, the phase displays the display text as column header and the status / expiry date as data.

6. **Confirm** button.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 8.1.1.3 GID-2671533 COMPLETED MODE (SR0305.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from Instruction (SR0305.8.1) process parameter (GID-2671844))

3. Confirm button (completed).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 8.1.2 Representation in Navigator (SR0305.4+)

The Navigator provides the following details:

### 8.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>

- Example:
  Vessel details

### 8.1.2.2 GID-2671535 INFORMATION COLUMN (SR0305.4.1)

- <Instruction text>

  - Example: This list shows all clean IBCs ...

  - Empty in case the instruction text is defined in HTML format

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Low |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 8.1.2.3 ACTION COLUMN

- There are no actions available.

### 8.1.3 Representation in Sub-report (SR0305.5+)

The sub-report contains the following information:

#### 8.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>

- <Completion time>

- <Unit procedure> / <operation> / <phase>

- <Work center> / <station> / <device> - <phase completion user>

#### 8.1.3.2 GID-2671538 SUB-REPORT ELEMENTS (SR0305.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Instruction text

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Medium |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 8.2 Business Logic (SR0305.2+)

The phase implements the following business logic.

### 8.2.1 GID-2669625 Show properties (SR0305.2.1)

- Function: Show property types and equipment graphs of equipment entities

- Trigger: Phase becomes active

- Postcondition: Property types and equipment graphs of equipment entities are displayed

| Step | # | Description |
|---|---|---|
| Phase activation | 10 | Phase displays its user interface according to the **Active mode (SR0305.1.2)** layout (GID-2671532). |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 8.3 Phase Parameters

The phase provides equipment parameters as process inputs (GID-2671539)and process parameters (GID-2669627).

### 8.3.1 Process Inputs (SR0305.6+)

#### 8.3.1.1 GID-2671539 EQUIPMENT PARAMETERS (SR0305.6.1)

Equipment parameters allow to define an equipment requirement as follows:

- by assigning an equipment class and
    - by assigning a specific property type (check against existence),
    - by setting specific property values (check against value, see **Technical Property Types and Editors (SR3071.8.7+)** in "Functional Requirement Specification Data Management" [A3] (GID-2667997)),
    - by defining a flexible rule, or
    - by defining a conditional rule.

---

For properties of the following data types, the property values cannot be accessed within rules:

- Equipment type
- Flexible tag definition
- Ranges
- Room cleaning rules
- Scale configuration
- Work center assignment

For details about rules, see **Expressions for Flexible Rules (SR3146.9.9.4.10)** and **Expressions for Conditional Rules (SR3146.9.9.4.12)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2667997).

---

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 8.3.2  Process Parameters (SR0305.8+)

The following process parameters define the behavior of the phase.

#### 8.3.2.1 INSTRUCTION TABLE-SPECIFIC PARAMETERS

8.3.2.1.1   INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Table layout | Choice list | Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**. |
| First column narrow | Boolean | Defines if the first column of the table shall be narrow. |
| Show all borders | Boolean | Defines if the borders of the table shall be visible. |

8.3.2.1.2   INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Column 1 | HTML text | Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags). |
| Column 2 | HTML text | |
| Column 3 | HTML text | |
| Column 4 | HTML text | |
| Column 5 | HTML text | |

### 8.3.2.2 INSTRUCTION LINK-SPECIFIC PARAMETERS

8.3.2.2.1   INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Instruction text | HTML text | Instruction text to be displayed.<br>For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671843).<br>Example: Refer to {SOP1270} for guidance.<br><br>Maximum length is 2000 characters (including HTML tags). |

8.3.2.2.2   INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Link text | Text | Text to be used as link.<br>For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute.<br>Including the brackets in the link text is optional.<br><br>Maximum length is 80 characters. |
| Link URL | Text | URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system.<br><br>Maximum length is 256 characters. |

### 8.3.2.3 BASIC PARAMETERS

8.3.2.3.1   GID-2671844 INSTRUCTION (SR0305.8.1)

| Attribute | Type | Comment |
|---|---|---|
| Text | HTML text | Instruction text to be displayed.<br>**Restriction**: Maximum length is 4000 characters (including HTML tags). |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 8.3.2.3.2 GID-2671845 MAXIMUM NUMBER OF ROWS (SR0305.8.2)

| Attribute | Type | Comment |
|---|---|---|
| Value | Long | Defines the number of rows (equipment entities and properties) to be displayed by the phase.<br>Range: [1..50]<br>Default setting: 10. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 8.3.2.3.3 GID-2671846 COLUMN DEFINITION (SR0305.8.3)

The phase allows up to nine bundle process parameters of this type.

| Attribute | Type | Comment |
|---|---|---|
| Attribute | String | Property type or equipment graph whose data shall be displayed. |
| Sorting order | Choice list | Defines the sorting order of the result list. In case different sorting orders are defined, the sorting order is evaluated from left to right. The equipment entity identifier is evaluated last.<br>Available settings: **No sorting**, **Ascending**, **Descending**.<br>Default setting: **No sorting**. |
| Position | Choice list | Defines the position of the column in the table. The options range between **Position 2** and **Position 10**, since an **Identifier** column that contains the identifier of the listed equipment entity is always the first column.<br>Default setting: **Position 2**. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

8.3.2.3.4  ATTRIBUTE SELECTION EDITOR (FRAMEWORK CAPABILITY)

The system provides an Attribute Selection editor for selecting a property type or an equipment graph property (status or expiry date).

## 8.4  Exceptions (SR0305.3+)

The phase supports user-defined, user-triggered (GID-2669629), system-triggered (GID-2669628), and post-completion exceptions (GID-2669630)and their configuration by means of process parameters (GID-2669627).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

### 8.4.1  System-triggered Exceptions

There are no system-triggered exceptions available.

### 8.4.2  User-triggered Exceptions

There are no user-triggered exceptions available.

### 8.4.3  Post-completion Exceptions

There are no post-completion exceptions available.

## 8.5  Information Messages

There are no information messages available.

## 8.6  Decisions

There are no decisions available.

## 8.7  Questions

There are no questions available.

## 8.8  Error Messages

There are no error messages available.

## 8.9  Output Variables (SR0305.9+)

The following output variables are available to reference the phase's output.

### 8.9.1 Instance count (Framework capability)

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

### 8.9.2 Start time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

### 8.9.3 Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

### 8.9.4 Identifier (Framework capability)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

# 9 Generate Template-based Equipment Phase (SR0306+)

The **Generate template-based equipment** phase allows to generate one or more equipment entities with attributes, properties, and equipment graphs based on a configured template equipment entity. The new generated equipment entities can inherit the **Approved** status of the template equipment entity and are thus immediately ready for use on the shop floor. The equipment entity can be identified by scanning its label, which is printed during the generation of the equipment entity.

Example use cases are:

- Generate an equipment entity for one-time use and track its lifecycle.
- Generate an equipment entity such as a prepared stamp for exclusive usage at a specific packaging step.

The instruction text is stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669637).

Anomalies that occur during processing are covered by the phase exception handling (GID-2668327)(e.g. adding a user-defined exception).

After completion the phase displays the instruction text in the Execution Window.

The Navigator displays the number of generated equipment entities.
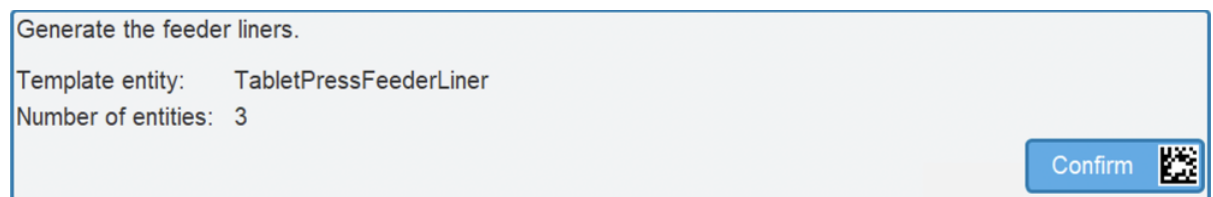


*Figure 23: Generate template-based equipment during execution*

## 9.1 Layout

The phase provides individual layouts for its representation during execution (GID-2669635), in the Navigator (GID-2669636), and in the sub-report (GID-2669637).

### 9.1.1 Representation during Execution (SR0306.1+)

The representation during execution depends on the phase mode.

### 9.1.1.1 GID-2671543 PREVIEW MODE (SR0306.1.1)

1. **<Instruction text>**
   **(taken from** Instruction (SR0306.8.1) **process parameter (GID-2671852))**

2. Template entity: <identifier taken from **Template entity (SR0306.8.3)** process parameter (GID-2671854)>

3. Number of entities: <value taken from **Number of entities (SR0306.8.3)** process parameter (GID-2671854)>

4. **Confirm** button (disabled).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Medium |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.1.1.2 GID-2671544 ACTIVE MODE (SR0306.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0306.8.1)** process parameter (GID-2671852))

3. Template entity: <identifier taken from **Template entity (SR0306.8.3)** process parameter (GID-2671854)>

4. Number of entities: <value taken from **Number of entities (SR0306.8.3)** process parameter (GID-2671854)>

5. **Confirm** button.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.1.1.3 GID-2671545 COMPLETED MODE (SR0306.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0306.8.1)** process parameter (GID-2671852)

3. Template entity: <identifier taken from **Template entity (SR0306.8.3)** process parameter (GID-2671854)>

4. Number of entities: <value taken from **Number of entities (SR0306.8.3)** process parameter (GID-2671854)>

5. In case of 1 generated entity:

   Generated entity: <identifier of the generated entity>

   In case of 2 generated entities:

   Generated entities: <identifier of first generated entity, identifier of second generated entity>

   In case of 3 and more generated entities:

   Generated entities: <identifier of first generated entity, identifier of second generated entity, ...>

6. **Confirm** button (completed).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.1.2  Representation in Navigator (SR0306.4+)

The Navigator provides the following details:

#### 9.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>

  - Example:
    Stamp generation

#### 9.1.2.2 GID-2671547 INFORMATION COLUMN (SR0306.4.1)

- <Number of entities generated>

  - Example: 3

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | Low |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 9.1.2.3 GID-3077435 ACTION COLUMN (SR0306.4.2)

Reprint. Reprints the entity label.
<identifier>

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.1.3  Representation in Sub-report (SR0306.5+)

The sub-report contains the following information:

### 9.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>

- <Completion time>

- <Unit procedure> / <operation> / <phase>

- <Work center> / <station> / <device> - <phase completion user>

### 9.1.3.2 GID-2671550 SUB-REPORT ELEMENTS (SR0306.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Instruction text

- Template entity

- Number of entities

- In case of 1 generated entity:
  Generated entity: <identifier of the generated entity>
  In case of 2 or more generated entities:
  Generated entities: <all identifiers of the generated entities>

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 9.2 Business Logic (SR0306.2+)

The phase implements the following business logic.

### 9.2.1 GID-3077413 Activate phase (SR0306.2.1)

- Function: Activate phase

- Trigger: Phase becomes active

- Postcondition: Phase is ready to be confirmed

| Step | # | Description |
|---|---|---|
| Phase activation | 10 | Phase displays its user interface according to the **Active mode (SR0306.1.2)** (GID-2671544). |
| Phase checks the completion mode | 20 | **Mode (SR0306.8.2)** process parameter is set to Automatic completion: Phase automatically continues with the **Confirm Phase (SR0306.2.2)** (GID-2669638). |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.2.2  GID-2669638 Confirm phase (SR0306.2.2)

- Function: Confirm phase

- Trigger: Confirm button used or automatic completion

- Postcondition: Phase is completed

| Step | # | Description |
|---|---|---|
| Phase checks number of entities to generate | 10 | If the number of entities according to the **Number of entities (SR0306.8.4)** process parameter (GID-2671856)is not defined, phase displays the **Number of entities to generate not defined (SR0306.3.6.6)** error message (GID-2669648).<br>If the defined number of entities according to the **Number of entities (SR0306.8.4)** process parameter (GID-2671856)is defined but < 1, phase displays the **Invalid number of entities to generate (SR306.3.6.1)** error message link. |
| Phase checks template entity definition | 20 | If no template entity is defined by the **Template entity (SR0306.8.3)** process parameter (GID-2671854), phase displays the **Not defined template entity (SR0306.3.6.4)** error message (GID-2669646). |
| Phase checks the existence of the template entity | 30 | If the template entity defined by the **Template entity (SR0306.8.3)** process parameter (GID-2671854)does not exist, phase displays the **Not existing template entity (SR0306.3.6.3)** error message (GID-2669645). |
| Phase checks template entity status | 40 | If the template entity status of the template defined by the **Template entity (SR0306.8.3)** process parameter (GID-2671854)is not allowed to be used (e.g. **Archived**), phase displays the **Not allowed template entity status (SR0306.3.6.2)** error message (GID-2669644). |
|  | 50 | If any of the checks failed, the phase is not confirmed. |

| Step | # | Description |
|------|---|-------------|
|      | 60 | If no check failed, the phase |
|      |    | <ul><li>generates the number of entities in the **Draft** status based on the template entity defined by the **Template entity (SR0306.8.3)** process parameter (GID-2671854).</li><li>The new entity identifier is defined by the template entity configuration.</li><li>If the **Inherit status from template (SR0306.8.5)** process parameter (GID-2671857)is enabled, the entity inherits the status of the template.</li><li>With each generated entity, its equipment label is printed.</li></ul> Phase is confirmed. |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 9.3  Phase Parameters

The phase provides process parameters (GID-2669639).

### 9.3.1  Process Parameters (SR0306.8+)

The following process parameters define the behavior of the phase.

#### 9.3.1.1 INSTRUCTION TABLE-SPECIFIC PARAMETERS

##### 9.3.1.1.1  INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|-----------|------|---------|
| Table layout | Choice list | Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**. |
| First column narrow | Boolean | Defines if the first column of the table shall be narrow. |
| Show all borders | Boolean | Defines if the borders of the table shall be visible. |

#### 9.3.1.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Column 1 | HTML text | Instruction text to be displayed in a column.<br>**Restriction**: Maximum length is 2000 characters (including HTML tags). |
| Column 2 | HTML text | |
| Column 3 | HTML text | |
| Column 4 | HTML text | |
| Column 5 | HTML text | |

### 9.3.1.2 INSTRUCTION LINK-SPECIFIC PARAMETERS

#### 9.3.1.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Instruction text | HTML text | Instruction text to be displayed.<br>For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671851).<br>Example: Refer to {SOP1270} for guidance.<br><br>Maximum length is 2000 characters (including HTML tags). |

#### 9.3.1.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

| Attribute | Type | Comment |
|---|---|---|
| Link text | Text | Text to be used as link.<br>For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute.<br>Including the brackets in the link text is optional.<br><br>Maximum length is 80 characters. |

| Attribute | Type | Comment |
|-----------|------|---------|
| Link URL | Text | URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system.<br><br>Maximum length is 256 characters. |

### 9.3.1.3 BASIC PARAMETERS

#### 9.3.1.3.1 GID-2671852 INSTRUCTION (SR0306.8.1)

| Attribute | Type | Comment |
|-----------|------|---------|
| Text | HTML text | Instruction text to be displayed.<br>**Restriction**: Maximum length is 4000 characters (including HTML tags). |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

#### 9.3.1.3.2 GID-2671853 MODE (SR0306.8.2)

| Attribute | Type | Comment |
|-----------|------|---------|
| Mode | Choice list | Defines the processing mode.<br>**Manual completion** (default): Operator confirms the phase.<br>**Automatic completion**: Phase automatically generates the equipment entities and is completed. |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.3.1.3.3 GID-2671854 TEMPLATE ENTITY (SR0306.8.3)

| Attribute | Type | Comment |
|---|---|---|
| Template entity | Text | Defines the template equipment entity.<br><br>The parameter retrieves and stores the identifier of the template equipment entity by selector or info flow. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.3.1.3.4 TEMPLATE EQUIPMENT ENTITY SELECTION EDITOR ()

The system provides a Template Equipment Entity Selection editor for selecting a template equipment entity.

### 9.3.1.3.5 GID-2671856 NUMBER OF ENTITIES (SR0306.8.4)

| Attribute | Type | Comment |
|---|---|---|
| Value | Long | Defines the number of equipment entities to be generated by the phase. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.3.1.3.6 GID-2671857 INHERIT STATUS FROM TEMPLATE (SR0306.8.5)

| Attribute | Type | Comment |
|---|---|---|
| Enabled | Boolean | Controls if the status of the template equipment entity shall be inherited to the generated equipment entities.<br>Default setting: **Yes** |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.3.1.4 CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

#### 9.3.1.4.1 GID-2671858 TEMPLATE ENTITY STATUS CHECK (SR0306.8.6)

| Attribute | Type | Comment |
|---|---|---|
| Minimum template entity status | Choice list | Defines the minimum template entity status required for the equipment entity generation.<br>Available settings: **Verification**, **Approved.**<br>Default setting: **Approved.** |
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.<br>Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment).**<br>Default setting: **High.** |
| Exception text | Text | Defines the exception description used during exception handling and within the batch record.<br>Maximum length is 250 characters. |

See also **Template entity status check (SR0306.3.2.1)** system-triggered exception (GID-2671556).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.3.1.5 CONFIGURATION OF POST-COMPLETION EXCEPTIONS

#### 9.3.1.5.1 GID-2671859 REPRINT ENTITY LABEL (SR0306.8.7)

| Attribute | Type | Comment |
|---|---|---|
| Risk assessment | Choice list | Defines the risk level of the exception and thus controls the related signature privilege.<br>Available settings: **None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment)**.<br>Default setting: **High**. |
| Exception text | Text | Defines the exception description used during exception handling and within the batch record.<br>Maximum length is 250 characters. |

See also **Reprint entity label (SR0306.3.3.1.1)** post-completion exception (GID-2671559).

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 9.4 Exceptions (SR0306.3+)

The phase supports user-defined, user-triggered (GID-2669641), system-triggered (GID-2669640), and post-completion exceptions (GID-2669642)and their configuration by means of process parameters (GID-2669639)..

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

### 9.4.1 System-triggered Exceptions (SR0306.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

#### 9.4.1.1 GID-2671556 TEMPLATE ENTITY STATUS CHECK (SR0306.3.2.1)

The phase checks if the defined minimum status for the template equipment entity is fulfilled according to the **Template entity status check (SR0306.8.6)** process parameter (GID-2671858).

Representation of the exception:

Exception dialog

- <Exception text>
  (taken from **Template entity status check (SR0306.8.6)** process parameter <u>(GID-2671858)</u>)
  Cannot use the <template entity identifier > template equipment entity, since it is in the <status> status.
  Required minimum status: <minimum status taken from **Template entity status check (SR0306.8.6)** process parameter <u>(GID-2671858)</u>>

Exception Window

- <Exception text>
  (taken from **Template entity status check (SR0306.8.6)** process parameter <u>(GID-2671858)</u>)
  Cannot use the <template entity identifier > template equipment entity, since it is in the <status> status.
  Required minimum status: <minimum status taken from **Template entity status check (SR0306.8.6)** process parameter <u>(GID-2671858)</u>>

  - Example:
    Template equipment entity status violation.
    Cannot use the Stamp_TPL_2 template equipment entity, since it is in the Verification status.
    Required minimum status: Approved

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.4.1.2 GID-2671557 TEMPLATE ENTITY STATUS CHECK - LOGIC (SR0306.3.2.1.1)

- Trigger: Check has failed

- Postcondition: Exception is recorded

| Step | # | Description |
|---|---|---|
| Operator accepts exceptional situation | 1-10 | Phase shows exception description to be signed. |
| Operator signs exception | 1-20 | Phase records the exception. |
| Operator does not accept exceptional situation | 2-10 | Phase records the cancel exception. |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 9.4.2 User-triggered Exceptions

There are no user-triggered exceptions available.

## 9.4.3 Post-completion Exceptions (SR0306.3.3+)

A post-completion exception is accessible via the Navigator and represented in the list of available post-completion exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following post-completion exceptions are available.

### 9.4.3.1 GID-2671558 Reprint entity label (SR0306.3.3.1)

The **Reprint entity label** exception allows an operator to reprint an equipment label for a generated equipment entity from the Navigator after the completion of the phase.

Representation of the exception:

- Instruction:
  To reprint an equipment label, enter the ID of the generated entity.
  Box for identifier input.
  **Confirm** button.

- <Exception text>
  (taken from **Reprint entity label (SR0306.8.7)** process parameter) (GID-2671859)
  Reprint the label of the entity: <entity identifier>

  - Example:
    Reprint of entity label required.
    Reprint the label of the entity: EQ000004528

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.4.3.2 GID-2671559 Reprint entity label - Logic (SR0306.3.3.1.1)

Trigger: Phase is completed, a label has been printed before

Postcondition: Label has been reprinted

| Step | # | Description |
|------|---|-------------|
| Operator triggers action | 10 | Phase displays Exception Window. |
| Operator confirms exception | 20 | If no entity identifier was entered, phase displays the **Entity for label reprint not defined (SR0306.3.6.7)** error message (GID-2669649). <br> If the entity with the entered identifier was not generated with this phase instance, phase displays the **Wrong entity for reprint (SR0306.3.6.5)** error message (GID-2669647). <br><br> Otherwise phase reprints the label. |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 9.5   Information Messages

There are no information messages available.

## 9.6   Decisions

There are no decisions available.

## 9.7   Questions

There are no questions available.

## 9.8   Error Messages (SR0306.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

### 9.8.1   GID-2669643 Invalid number of entities to generate (SR0306.3.6.1)

| UI text | Comment |
|---------|---------|
| The number of generated entities must be greater than zero. | Message pack: PhaseEqmEqGenTemplateBased<version> <br> Message ID: InvalidNumberOfGeneratedEntities_ErrorMsg |

| Attribute | Value |
|-----------|-------|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.8.2 GID-2669644 Not allowed template entity status (SR0306.3.6.2)

| UI text | Comment |
|---|---|
| The template entity <identifier> cannot be used in the <template entity status> status. | Message pack: PhaseEqmEqGenTemplateBased<version><br>Message ID: TemplateEntityArchived_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.8.3 GID-2669645 Not existing template entity (SR0306.3.6.3)

| UI text | Comment |
|---|---|
| The template entity <identifier> does not exist. | Message pack: PhaseEqmEqGenTemplateBased<version><br>Message ID: TemplateEntityDoesNotExist_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.8.4 GID-2669646 Not defined template entity (SR0306.3.6.4)

| UI text | Comment |
|---|---|
| There is no template entity defined. | Message pack: PhaseEqmEqGenTemplateBased<version><br>Message ID: UndefinedTemplateEntity_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.8.5 GID-2669647 Wrong entity for reprint (SR0306.3.6.5)

| UI text | Comment |
|---|---|
| The entity <identifier> was not generated by this phase run. | Message pack: PhaseEqmEqGenTemplateBased<version><br>Message ID: EntityNotGeneratedByThisPhase_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.8.6  GID-2669648 Number of entities to generate not defined (SR0306.3.6.6)

| UI text | Comment |
|---|---|
| There is no number of entities defined. | Message pack: PhaseEqmEqGenTemplateBased<version><br>Message ID: UndefinedNumberOfGeneratedEntities_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.8.7  GID-2669649 Entity for label reprint not defined (SR0306.3.6.7)

| UI text | Comment |
|---|---|
| Please enter the entity identifier. | Message pack: PhaseEqmEqGenTemplateBased<version><br>Message ID: UndefinedEntity_ErrorMsg |

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

## 9.9  Output Variables (SR0306.9+)

The following output variables are available to reference the phase's output.

### 9.9.1  Instance count (Framework capability)

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

### 9.9.2  Start time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

### 9.9.3  Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

### 9.9.4  Identifier (Framework capability)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

### 9.9.5  GID-2669654 Equipment object (SR0306.9.1)

- Data type: IMESS88Equipment

- Usage: The output variable provides the first generated equipment entity. This is the output to use in subsequent phases for accessing data of the equipment object, such as displaying its status or a property.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.9.6  GID-2669655 Equipment ID (SR0306.9.2)

- Data type: String

- Usage: The output variable provides the identifier of the identified equipment entity for displaying it as text.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

### 9.9.7  GID-2669656 Number of generated entities (SR0306.9.3)

- Data type: Long

- Usage: The output variable provides the number of generated equipment entities.

| Attribute | Value |
|---|---|
| MES-Business: GxP relevance | Yes |
| MES-Business: Business Impact | High |
| MES-Compliance: 21 CFR Part 11 relevance | No |

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# 10 Reference Documents

The following documents are available from the Rockwell Automation Download Site.

| No. | Document Title | Part Number |
|-----|----------------|-------------|
| A1 | FT PharmaSuite Functional Requirement Specification Execution Framework | PSFRSEF-RM007B-EN-E |
| A2 | FT PharmaSuite Functional Requirement Specification Recipe and Workflow Management | PSFRSRD-RM011B-EN-E |
| A3 | FT PharmaSuite Functional Requirement Specification Data Management | PSFRSDM-RM007B-EN-E |
| A4 | FT PharmaSuite Technical Guide Configuration & Extension - Volume 4 | PSCEV4-GR011B-EN-E |

**TIP**

To access the Rockwell Automation Download Site, you need to acquire a user account from Rockwell Automation Sales or Support.

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# 11 Document Information

The document information covers various data related to the document.

## 11.1 Approval

This document has been approved electronically via the Rockwell Automation Document Management System (DMS). The required approvers of this document include the following:

| Name | Role |
|---|---|
| Norbert Ern | Product Owner |
| Wolfgang Schmitt | Technical Lead |
| Ignaz Wangler | Test Lead |

## 11.2 Version Information

| Object | Version |
|---|---|
| FT PharmaSuite | 11.01.00 |
| Identify Equipment | 11.0 |
| Change Equipment Status | 11.1 |
| Trigger Graph Transition | 11.1 |
| Separate Equipment | 11.0 |
| Unbind Equipment | 11.0 |
| Generate Template-based Equipment | 11.0 |
| Show Equipment List | 11.0 |
| Functional Requirement Specification | 1.0 |

# 12 Appendix A - Revision History

## 12.1 Updated Requirements

GID-2668267 Phases

GID-2671822 Instruction (SR0300.8.1)

GID-2667991 Change Equipment Status Phase (SR0310+)

GID-2671437 Preview mode (SR0310.1.1)

GID-2671449 Instruction (SR0310.8.1)

GID-2671453 Equipment data mismatch (SR0310.8.4)

GID-2671454 Force status (SR0310.8.5)

GID-2667992 Trigger Graph Transition Phase (SR0311+)

GID-2671475 Instruction (SR0311.8.1)

GID-2671479 Allowed triggers (SR0311.8.4)

GID-2671481 Equipment data mismatch (SR0311.8.5)

GID-2671482 Status transition failed (SR0311.8.6)

GID-2669586 New status (SR0311.9.5)

GID-2671499 Instruction (SR0312.8.1)

GID-2671510 Active mode (SR0320.1.2)

GID-2671512 Phase column (Framework capability)

GID-2671521 Instruction (SR0320.8.1)

GID-2671844 Instruction (SR0305.8.1)

GID-2671543 Preview mode (SR0306.1.1)

GID-2671544 Active mode (SR0306.1.2)

GID-2671545 Completed mode (SR0306.1.3)

GID-2671852 Instruction (SR0306.8.1)

## 12.2 Added Requirements

**None**


## 12.3 Deleted Requirements

**None**

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